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(71) Applicant *(for all designated States except US)*: **CONOR MEDSYSTEMS, INC.** [US/US]; 401 Camberly Way, Redwood City, CA 94061 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SHANLEY, John, F.** [US/US]; 401 Camberly Way, Redwood City, CA 94061 (US).

(74) Agent: **PETERSON, James, W.**; Burns, Doane, Swecker & Mathis, LLP, P.O. Box 1404, Alexandria, VA 22313-1404 (US).

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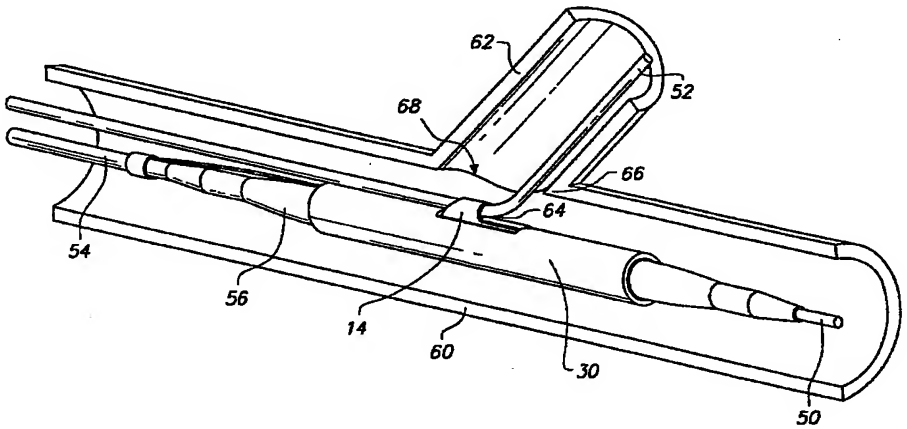
(54) Title: EXPANDABLE MEDICAL DEVICE DELIVERY SYSTEM AND METHOD



(57) Abstract: A delivery system and method are provided for accurately locating, orienting, and implanting expandable tissue supporting devices at a lumen junction or bifurcation in a body lumen. For example, the system may be used to deliver a tissue supporting device to a bifurcated artery such that, on expansion, the tissue supporting device provides side ports of a specific size and geometry to accommodate bifurcations in the artery. The delivery system is capable of accurately orienting these side ports both radially and longitudinally with respect to branch lumen openings of the artery. The delivery system achieves orientation by utilizing a guide member which is positioned to extend from the side port feature of the tissue supporting device. The guide member is tracked along a guidewire which extends into the branch lumen, ultimately orienting the side port of the tissue supporting device properly at the branch lumen opening. After expansion of the tissue supporting device, the guide member drops out of the enlarged side port and is withdrawn.

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EXPANDABLE MEDICAL DEVICE DELIVERY SYSTEM AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a delivery system and method for delivering tissue supporting medical devices, and more particularly to a system and method for implanting expandable, non-removable devices at the junction of two or more bodily lumens in a living animal or human to support the organs and maintain patency.

2. Summary of the Related Art

In the past, permanent or biodegradable devices have been developed for implantation within a body passageway to maintain patency of the passageway. These devices are typically introduced percutaneously, and transported transluminally until positioned at a desired location within the body passageway. The devices are then expanded either mechanically, such as by the expansion of a mandrel or balloon positioned inside the device, or expand themselves by releasing stored energy upon actuation within the body. Once expanded within the lumen, these devices, called stents, become encapsulated within the body tissue and remain a permanent implant.

Frequently, the area to be supported by such devices is located at or near the junction of two or more lumens, called a bifurcation. In coronary angioplasty procedures, for example, it has been estimated that 15% to 20% of cases involve reinforcing the area at the junction of two arteries. Conventional stent implantation at such a junction results in at least partial blockage of the branch artery, affecting blood flow and impeding access to the branch artery for further angioplasty procedures.

Known techniques for treating bifurcations generally deliver a mesh tissue supporting device into the artery and position the device over the bifurcation. According to the known methods, a surgeon then attempts to create one or more branch lumen access

holes by inserting a balloon through the sidewall of the mesh device, and then inflating the balloon to simply push the local features of the mesh aside. These techniques are inherently random in nature: the exact point of expansion in the device lattice cannot be predicted, and the device may or may not expand satisfactorily at that point. Tissue support provided by these known techniques for treating bifurcated arteries is similarly unpredictable. In addition, the effectiveness of such procedures is limited because many mesh devices are unable to accommodate such expansion at random locations in the device structure. Further, prior art tissue supporting device delivery systems are unable to accurately position specific device features over the branch artery opening.

Prior art tissue supporting devices for bifurcations generally have not attempted to orient the device radially at the branch lumen opening. Rather, these stents included a section along their axis or at one end at which several enlarged expansion cells were distributed uniformly around the stent circumference. The presumption was that after stent insertion, one or the other of these cells would be oriented closely enough with the branch lumen opening that the subsequent procedures mentioned above would clear the opening. One example of such a device is the Jostent® bifurcation stent design which has an 8 cell circumferential construction over half the stent length and either 2 or 3 rows of larger cells which can be post-dilated to allow access for placement in a bifurcated vessel. One problem with this technique is that the resulting density of stent features at the area of the bifurcation is so low that there is very little stent strength around the rest of the circumference of the main artery for tissue support. Thus, the lumen junction area, which requires the greatest tissue support, actually gets the lowest support. For the same reason, such tissue supporting devices also provide a low ratio of tissue coverage (metal-to-tissue area ratio) in the junction area. Low metal coverage and the resulting tissue prolapse are associated with higher restenosis rates.

Another method for deploying a stent in a bifurcating vessel is described in International Application WO98/19628. According to this method, a main stent having a substantially circular side opening and a flared stent having a flared end are used together

to treat a bifurcating vessel in a two step process. In a first step, the main stent is positioned using an inflatable balloon catheter in the interior of the main stent and a stabilizing catheter extending through the side opening of the stent. The stabilizing catheter is used to place the side opening in the main stent at the opening to the branch vessel. The main stent is then expanded and the flared stent is inserted through the side opening into the vessel bifurcation. One drawback of this method is the difficulty in positioning the side opening of the main stent at a proper longitudinal and radial position at the vessel bifurcation. Another drawback of this system is the flared stent which is difficult to form and position, and may tend to protrude into the blood stream causing thrombosis.

In view of the drawbacks of the prior art bifurcated tissue supporting systems, it would be advantageous to have a delivery system capable of accurately locating a side port feature of a tissue supporting device at a branch lumen opening, in both the longitudinal and radial directions.

It would further be advantageous if the same delivery system could also be used to accurately install and orient a branch lumen second tissue supporting device.

SUMMARY OF THE INVENTION

The invention includes expandable tissue supporting devices for use at lumen junctions or bifurcations, and a delivery system and method for accurately locating, orienting, and implanting the tissue supporting devices at the lumen junction or bifurcation.

In accordance with one aspect of the present invention, a system is described for delivery of a tissue supporting device to a bifurcated body lumen. The system includes a catheter with an inflatable balloon configured to deliver an expandable tissue supporting device to the lumen, a guide member received on a side of the balloon and connected to the catheter, and a branch lumen guidewire extending along an exterior of the balloon and longitudinally slidable in the guide member.

In accordance with another aspect of the invention, a guide member is described for use in delivery of a tissue supporting device to a bifurcated body lumen in a desired longitudinal and radial position. The guide member includes a guide loop for receiving a guidewire, means for securing the guide loop to a catheter, and at least one tab extending from the guide loop for holding the guide loop in position in a side hole of a tissue supporting device to be delivered.

In accordance with a further aspect of the invention, a method of delivering of a tissue supporting device to a bifurcated body lumen includes the steps of:

providing an expandable tissue supporting device in an unexpanded configuration, the tissue supporting device having a side hole;

positioning a guide member in the side hole;

positioning a side branch guidewire in a body lumen with a distal end of the side branch guidewire extending into a side branch of a bifurcation;

delivering the tissue supporting device into the body lumen by tracking the guide member along the side branch guidewire;

positioning the tissue supporting device with the side hole aligned radially and longitudinally with an opening of the side branch; and

expanding the tissue supporting device.

BRIEF DESCRIPTION OF DRAWINGS

The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

FIG. 1 is a perspective view of a guide member in accordance with the present invention;

FIG. 2a is a side view of an unexpanded tissue supporting device with a side port, the device has been laid flat for ease of illustration;

FIG. 2b is a simplified, perspective view of the cylindrical tissue supporting device of FIG. 2a;

FIG. 3 is a perspective view of the guide member of FIG. 1 mounted in the side port of the tissue supporting device of FIGS. 2a and 2b;

FIG. 4 is a perspective view of the tissue supporting device of FIGS. 2a and 2b as it is inserted to a junction of two arteries with a balloon catheter and two guidewires;

FIG. 5 is a perspective view illustrating a first step of the implantation sequence: expansion of the distal end of the tissue supporting device;

FIG. 6 is a perspective view illustrating a second step of the implantation sequence: withdrawal of the branch lumen guidewire;

FIG. 7 is a perspective view illustrating a third step of the implantation sequence: expansion of the side port area and proximal end of the tissue supporting device;

FIG. 8 is a perspective view illustrating a fourth step of the implantation sequence: deflation and withdrawal of the balloon and guide loop;

FIG. 9 is a perspective view of a guide member with an auxiliary guide loop in accordance with the present invention; and

FIG. 10 is a perspective view of the guide member of FIG. 9 mounted in a tissue supporting device having two side ports.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention involves a system and method for delivery of a tissue supporting device to a bifurcated artery such that, on expansion, the tissue supporting device provides side ports of a specific size and geometry to accommodate bifurcations in the artery. The delivery system is capable of accurately orienting these side ports both radially and longitudinally with respect to branch lumen openings of the artery. The delivery system achieves orientation by utilizing a guide member 10 which is positioned to extend from the side port feature of the tissue supporting device. The tissue support device is delivered to the artery on a balloon catheter which is used for expansion of the device. The guide

member 10 is tracked along a side branch guidewire which extends into the branch lumen, ultimately orienting the side port of the tissue supporting device properly at the branch lumen opening. While the tissue supporting device having the side port is expanded, the guide member 10 holds the tissue supporting device in the proper position. After expansion, the guide member 10 drops out of the enlarged side port and is withdrawn with the balloon catheter assembly.

FIG. 1 shows one embodiment of a guide member 10 in accordance with the present invention. The device 10 includes a main body 12 of which is preferably formed as a unitary piece comprising a loop 14, a spacer section 16, and two tabs 18. The inner diameter of the loop 14 is just large enough to provide clearance for a guidewire which will pass through the loop. The loop 14, spacer section 16, and tabs 18 may be integrally formed from a single piece of tubing. The radius of the tabs 18 conforms generally to the inner radius of the unexpanded tissue supporting device in which the guide loop will be mounted.

The main body 12 of the guide member 10 is attached to a crimping lug 22 via a long, flexible tether 20. The tether 20 can be a simple wire attached to the main body 12 and crimping lug 22 at either end, or can be integrally formed from the same tube as the main body 12 and the crimping lug 22.

The guide member 10 is preferably made radiopaque by one of several available methods. For example, the wall thickness of the tube may be made thick enough for good radio opacity. Alternatively, the guide loop may be made from, plated, or coated with a radiopaque material. This is not objectionable since the guide member is withdrawn immediately after the procedure and does not become a permanent implant. When the radiopaque guide member is crimped into the side port of the tissue supporting device as described in further detail below, the exact location of the side port will be clearly visible on the fluoroscope.

A preferred tissue supporting device for use in the present invention provides several capabilities not normally found in conventional stents. The tissue supporting device

should provide a side port feature which will securely clamp the guide member 10 in the side port when the tissue supporting device itself is crimped to the catheter balloon. The side port should expand to some desired shape and release the guide member when the tissue supporting device is expanded. The tissue supporting device should also be capable of differential expansion; i.e. different areas of the device should expand at different balloon pressures, giving the device the ability to open in a specific sequence.

FIG. 2a shows a portion of one embodiment of a cylindrical, expandable tissue supporting device 30 which has been laid flat for ease of illustration. The device 30 of FIG. 2a is shown in an unexpanded configuration and includes a rectangular side hole or port 32. FIG. 2b shows a simplified cylindrical view of the expandable tissue supporting device 30 of FIG. 2a, with the side port feature 32 shown as a rectangular hole in one side. This embodiment of the tissue supporting device 30 relies on the use of ductile hinges which interconnect a plurality of struts to achieve the desired performance features. Tissue supporting devices of the type shown in FIG. 2a are described in further detail in U.S. Patent Application Serial No. 09/183,555, filed October 29, 1998, and in U.S. Patent Application Serial No. 09/315,892, filed on May 20, 1999 which are both incorporated herein by reference in their entirety.

As shown in FIGS. 2a and 2b, the side hole 32 initially takes the form of a rectangular hole in the unexpanded tissue supporting device 30. The side hole 32 is bordered by six struts 34 that are in turn linked by ductile hinges 36. The rectangular side hole 32 fits the profile of the guide loop feature 10 closely, and the excellent crimping properties of the ductile hinges allow the hole to close tightly around the guide loop feature when the tissue supporting device 30 is crimped onto the catheter balloon. When the tissue supporting device 30 is expanded, such as by inflation of a balloon, the side hole feature 32 will expand to form an octagonal hole, releasing the guide member 10.

In the tissue supporting device 30 of FIG. 2a, the ductile hinges 38 linking struts 40 on the left or proximal end of the device are wider than the ductile hinges 42 linking struts 44 on the right or distal end of the device. The width of the ductile hinges is measured in

the circumferential direction of the device 30. As balloon pressure is increased during expansion of the device 30 the distal end of the device will open before the proximal end due to the different configuration of the ductile hinges at the two ends of the device. The tissue supporting device 30 should be selected so that the device is capable of expansion beyond a nominal expansion which corresponds to an interior diameter of the lumen to be supported. This will ensure that the tissue supporting device 30 can be expanded to the desired diameter of the expanded lumen allowing for variations in artery diameters. Allowing for some additional expansion beyond the nominal expansion of the tissue support device 30 means that some of the struts around the circumference of the device will not reach their locking angle when the device has been installed. Accordingly, if the struts 48 all open to their full extent before the struts 34 that border the side hole 32, this may result in the side hole not being fully opened when the tissue supporting device is installed. The partially opened side hole may partially block access to the branch artery. Accordingly, the ductile hinges 36 connecting the struts 34 that border the side hole 32 are preferably somewhat narrower than the ductile hinges 46 of the surrounding struts 48. This will guarantee that the hole feature opens to its final shape before the surrounding struts 48 reach full expansion.

The present invention will be described with respect to a tissue supporting device having ductile hinges such as the device illustrated in FIG. 2a. However, it should be understood that the system and method according to the present invention may also be used for delivery of other known tissue supporting devices having side holes.

FIG. 3 illustrates the guide member 10 inserted in the tissue supporting device 30 such that the loop 14 projects out through the rectangular side hole 32 and is retained in the hole. The guide member 10 is retained in the side hole 32 by the tabs 16 which are trapped between the tissue supporting device 30 and a balloon catheter assembly.

As shown in FIG. 4, the tissue supporting device 30 and guide member 10 are mounted on a catheter balloon 56 and the tissue supporting device 30 is crimped down onto the balloon in a known manner. The crimping process causes the strut elements 34 of the

rectangular side hole 32 in the tissue supporting device 30 to close around the guide loop 10, locking the guide loop into place in the side hole. The crimping lug 22 of the guide loop 10 is crimped around the catheter 54 just below the proximal end of the balloon assembly, securing the guide member 10 to the catheter. The catheter and tissue supporting device assembly is now ready for insertion and deployment.

The guide member 10 may take on other configurations as long as the guide member forms a short tube or loop positioned on or secured to the balloon/catheter assembly in such a way that it passes out through the side hole of the tissue supporting device when the device is crimped or otherwise secured on the balloon 56. For example, the guide member may be formed from a plastic tube and secured directly to the balloon, such as, by an adhesive.

Prior to insertion of the catheter and tissue supporting device assembly, two catheter guidewires are installed by the operator. A first guidewire 50 follows the main artery 60 as shown in FIG. 4, and a second guidewire 52 is inserted into the branch artery 62. The catheter 54 having the tissue supporting device 30 mounted on the balloon 56 at the distal end of the catheter is tracked over the main artery guidewire 50. The branch artery guidewire 52 is threaded through the guide loop 12 that projects through the top of the tissue supporting device 30. The assembly is then fed through a catheter guide tube (not shown) to the site of the bifurcation 68. As the catheter assembly approaches the bifurcation 68, the clevis 64 formed by the tissue supporting device 30 and the branch artery guidewire 52 comes to rest against the distal side 66 of the branch artery opening. The guide loop 14, and thus the side port 32 of the tissue supporting device 30 in which it is crimped, is now located directly under the branch artery opening, and the device is ready for deployment. The spacer 16 spaces the guide loop a predetermined distance from the distal edge of the side hole 32 so that the side hole will be properly aligned with the opening of the bifurcation 68.

To deploy the tissue supporting device 30, pressure is increased in the catheter balloon 56 until the distal end 70 of the tissue supporting device expands to the lumen

diameter of the main artery 60. This procedure locks the tissue supporting device 30 in place in the desired radial and longitudinal orientation as shown in FIG. 5.

Next, the side branch guidewire 52 is withdrawn from the branch lumen 62 and the guide loop 14, and retracted to a position slightly behind the proximal end of the catheter balloon 56 as shown in FIG. 6. The side branch guidewire 52 is free to move back and forth longitudinally because the proximal end of the tissue supporting device 30 has not been expanded. It is desirable to withdraw the side branch guidewire 52 temporarily while completing expansion of the proximal end of the tissue supporting device 30 to avoid pinning the side branch guidewire between the expanded tissue supporting device 30 and the lumen wall. This is the reason that differential expansion capability is beneficial in the tissue supporting device 30.

After withdrawal of the side branch guidewire 52, pressure in the catheter balloon 56 is increased further, until the side port area and the proximal end of the tissue supporting device 30 expand to their full extent. During expansion of the side port area, the spacer 16 and loop 14 maintain the longitudinal dimension of the side hole 32 and prevent longitudinal contraction of the side hole during expansion. The main artery tissue supporting device 30 is now fully deployed with a fully open side port 32a of specific geometry positioned over the branch lumen opening, and a full complement of strut elements deployed around the remainder of the artery opposite the side port to provide good tissue support as shown in FIG. 7.

The catheter balloon 56 is then deflated, allowing the guide member 10 to drop out of the enlarged side port 32a. The deflated catheter/balloon assembly is then withdrawn, pulling the guide member 10 along with it via the tether 18 and crimping lug 22 as shown in FIG. 8. After the catheter/balloon/guide loop assembly has been withdrawn, the side branch guidewire 52 may be reinserted through the tissue supporting device enlarged side hole 32a and into the branch lumen 62 for subsequent procedures.

The orientation accuracy of the delivery system can be improved by the addition of one or more auxiliary guide loops to the guide member as illustrated in FIGS. 9 and 10.

The guide member 70 as shown in FIG. 9 includes the main loop 14 with the spacer section 16 and tabs 18, and an auxiliary loop 72. The auxiliary loop 72 is also provided with tabs 74 which conform generally to the inner radius of the unexpanded tissue supporting device in which the guide loop will be mounted. The auxiliary loop 72 is connected the main loop 14 by a first tether 76 and is connected to the crimping lug 22 by a second tether 78. As shown in FIG. 10, the auxiliary loop 72 extends through a second side port feature 80 in the tissue supporting device 30. The additional one or more auxiliary loops 72 are located proximal to the primary guide loop 14. The installation procedure for the tissue supporting device 30 using the guide member 70 shown in FIGS. 9 and 10 would be performed in the same manner as discussed above with respect to the embodiment employing a single guide loop, however, the side branch guidewire 52 extends through both the main guide loop 14 and the auxiliary loop 72.

One common procedure to follow implantation of the tissue supporting device 30 into the main lumen would be implantation of a second tissue supporting device in the branch lumen 62. A procedure very similar to the one just outlined could be used to accomplish this task, by simply reversing the roles of the main lumen and branch lumen guidewires. As above, a guide member is inserted into the side port of a second tissue supporting device, and the assembly is crimped down on a conventional catheter balloon. In this case, the catheter and tissue supporting device assembly is mounted on the side branch guidewire 52, and the main artery guidewire 50 is threaded through the guide member. As before, the entire assembly is fed to the bifurcation site, where the clevis formed by the tissue supporting device and main artery guidewire 50 comes to rest against the distal side of the branch lumen opening. In this case, the side-port border-struts of the previously implanted tissue supporting device 30 are also in place to provide an even more accurate stop for aligning the side hole edge of the incoming tissue supporting device at the distal side of the bifurcation.

The tissue supporting device deployment sequence for deploying the second device would now proceed as before: the distal end of the branch tissue supporting device would

be expanded in the branch artery, anchoring the tissue supporting device in position, and the main artery guidewire 50 would be retracted below the proximal end of the catheter balloon. The unexpanded proximal end of the second tissue supporting device now extends back into the main artery, with the tissue supporting device side port facing downstream in the main artery.

When expansion of the second tissue supporting device is completed, the proximal end of the second tissue supporting device will be implanted in the main artery, with the second tissue supporting device bent around the proximal side of the branch artery orifice. The side port of the second tissue supporting device will open exactly opposite this bend, since the leading edge of the side port was initially located at the bifurcation junction as described above. The side port thus opens to permit flow through the main artery, and the tissue supporting device struts arrayed opposite the side port provide support to the proximal side of the branch artery orifice (the bend area). After implantation has been completed, the catheter/balloon/guide loop assembly is withdrawn, completing the procedure.

Although the invention has been described with respect to providing support for bifurcated lumens in arteries, it should be understood that the invention may also be used to provide support for bifurcations in other bodily lumens.

While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention.

What is claimed is:

1. A system for delivery of a tissue supporting device to a bifurcated body lumen, the system comprising:

a catheter with an inflatable balloon, the inflatable balloon configured to deliver an expandable tissue supporting device to the lumen;

a guide member received on a side of the balloon and connected to the catheter; and

a branch lumen guidewire extending along an exterior of the balloon and longitudinally slidable in the guide member.

2. The system of Claim 1, wherein the guide member extends radially from the side of the balloon and is arranged to be received in a side hole of a tissue supporting device mounted on the balloon.

3. The system of Claim 1, wherein the guide member includes a guide loop.

4. The system of Claim 1, further comprising a tissue supporting device mounted on the balloon, and the branch lumen guidewire is slidable along an exterior of the tissue supporting device.

5. The system of Claim 4, wherein the guide member is positioned between the tissue supporting device and the balloon and is crimped in place by crimping of the tissue supporting device onto the balloon.

6. The system of Claim 1, wherein the guide member includes a fastener connected to the catheter.

7. The system of Claim 6, wherein the fastener includes a crimping lug which is connected to a body of the guide member by a tether.

8. The system of Claim 1, wherein the guide member includes first and second guide loops which are arranged to be received in side holes of a tissue supporting device mounted on the balloon.

9. A guide member for use in delivery of a tissue supporting device to a bifurcated body lumen in a desired longitudinal and radial position, the guide member comprising:

a guide loop for receiving a guidewire;

means for securing the guide loop to a catheter; and

at least one tab extending from the guide loop for holding the guide loop in position in a side hole of a tissue supporting device to be delivered.

10. The guide member of Claim 9, wherein the at least one tab is a curved member having a radius of curvature which corresponds substantially to an inner radius of the tissue supporting device to be delivered.

11. The guide member of Claim 9, wherein the guide loop and at least one tab are formed from a single piece of tubing.

12. The guide member of Claim 9, wherein the means for securing the guide loop to a catheter includes a crimping lug which is connected to the guide loop by a tether.

13. The guide member of Claim 9, further comprising a spacer member connected to the guide loop and configured to space the guide loop a predetermined distance from a distal edge of the side hole of the tissue supporting device when the guide loop is positioned in the side hole of the tissue supporting device.

14. The guide member of Claim 9, further comprising an auxiliary guide loop positioned proximally of the guide loop.

15. A method of delivering of a tissue supporting device to a bifurcated body lumen comprising:

providing an expandable tissue supporting device in an unexpanded configuration, the tissue supporting device having a side hole;

positioning a guide member in the side hole;

positioning a side branch guidewire in a body lumen with a distal end of the side branch guidewire extending into a side branch of a bifurcation;

delivering the tissue supporting device into the body lumen by tracking the guide member along the side branch guidewire;

positioning the tissue supporting device with the side hole aligned radially and longitudinally with an opening of the side branch; and

expanding the tissue supporting device.

16. The method of Claim 15, wherein the tissue supporting device is delivered and expanded by a balloon catheter.

17. The method of Claim 15, wherein the guide member is positioned in the side hole such that a guide loop of the guide member extends out of the side hole of the tissue supporting device.

18. The method of Claim 15, wherein the tissue supporting device is expanded by expanding a distal segment of the tissue supporting device, removing the side branch guidewire from the guide member, and then expanding a proximal segment of the tissue supporting device.

19. The method of Claim 15, further comprising delivering a second tissue supporting device to support the side branch of the bifurcation.

20. The method of Claim 19, wherein the second tissue supporting device includes a side hole and is delivered by a method comprising:

positioning a second guide member in the side hole;

positioning a guidewire in the body lumen with a distal end of the guidewire extending into the expanded tissue supporting device;

delivering the second tissue supporting device into the body lumen by tracking the second guide member along the guidewire;

positioning the second tissue supporting device with the side hole aligned radially and longitudinally with an opening of a main branch of the bifurcation; and

expanding the second tissue supporting device.

21. The method of Claim 15, wherein the delivery of the tissue supporting device is visualized by fluoroscopy.

22. The method of Claim 17, wherein an auxiliary guide loop extends out of an auxiliary side hole of the tissue supporting device.

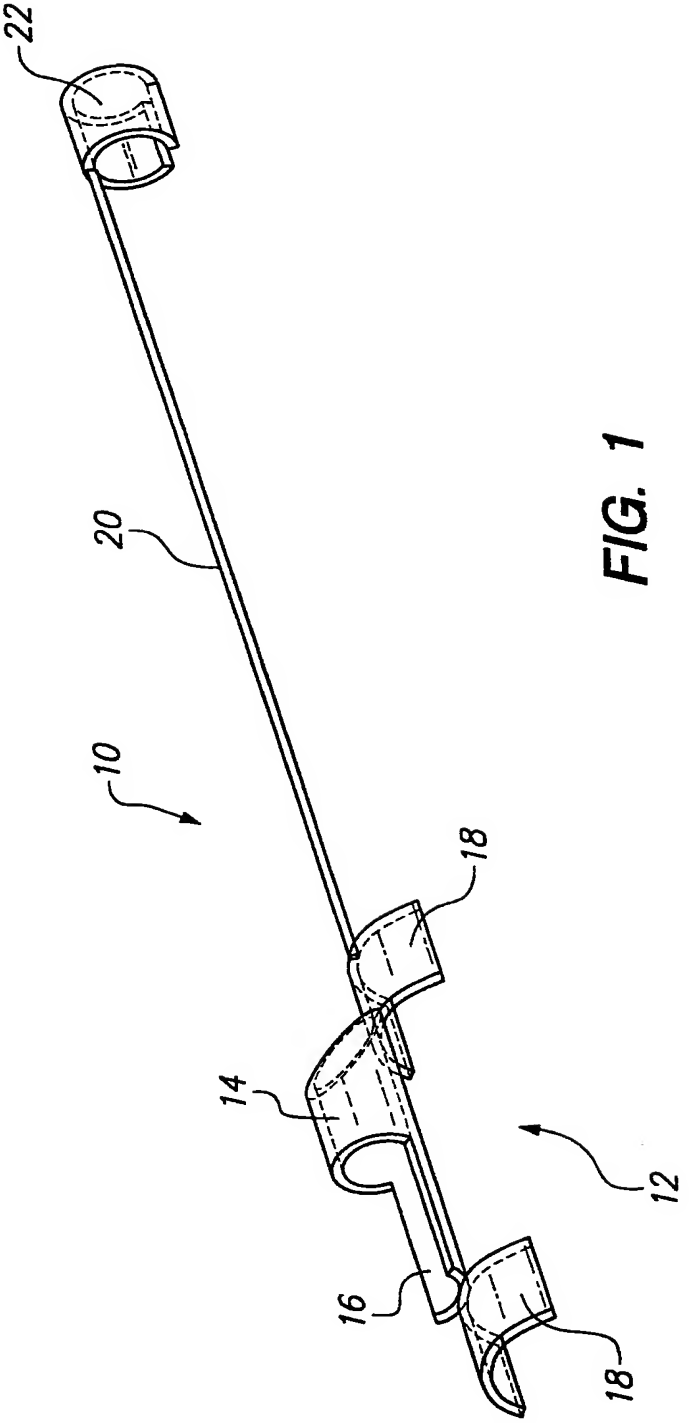

FIG. 1

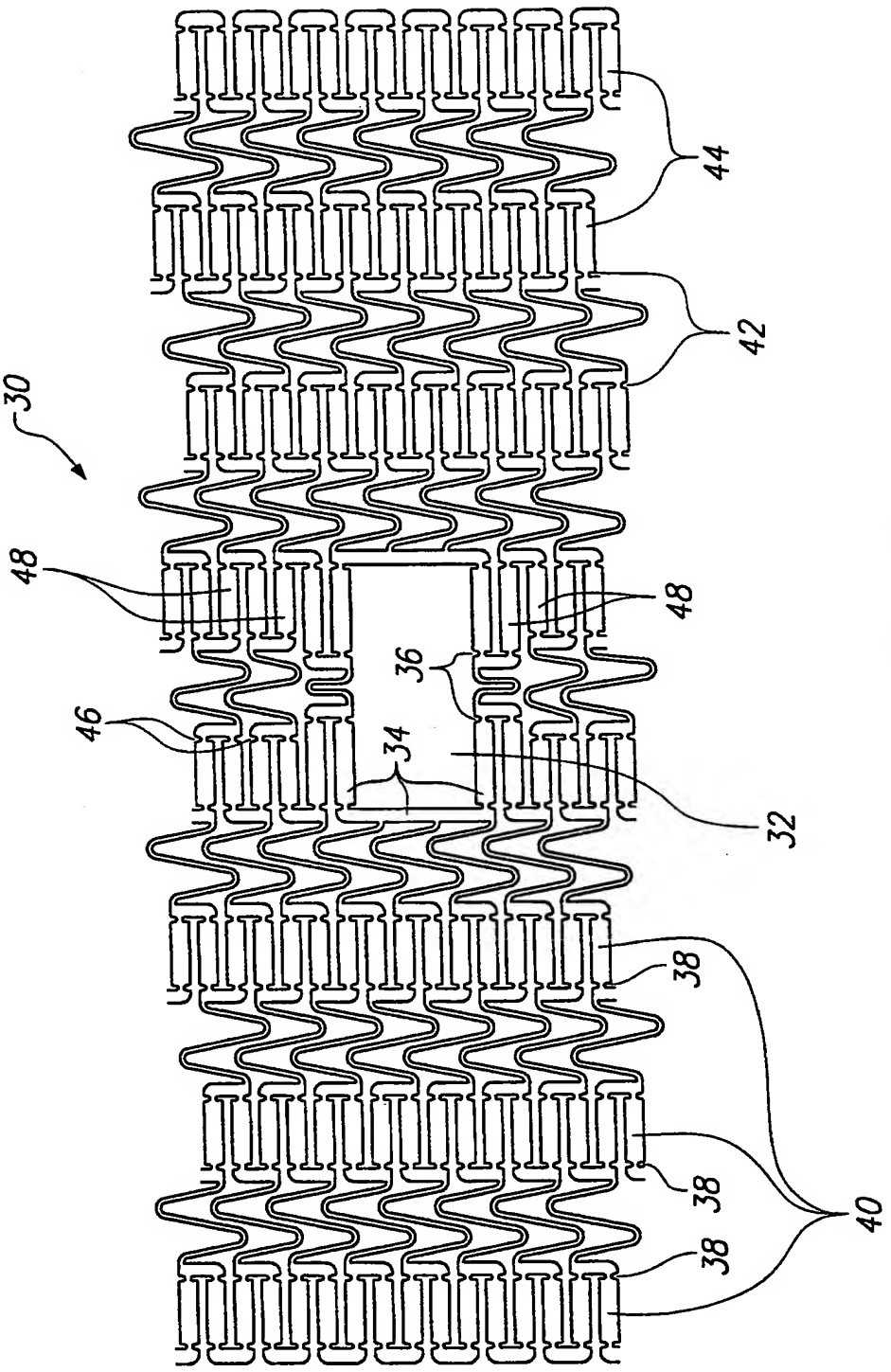

FIG. 2A

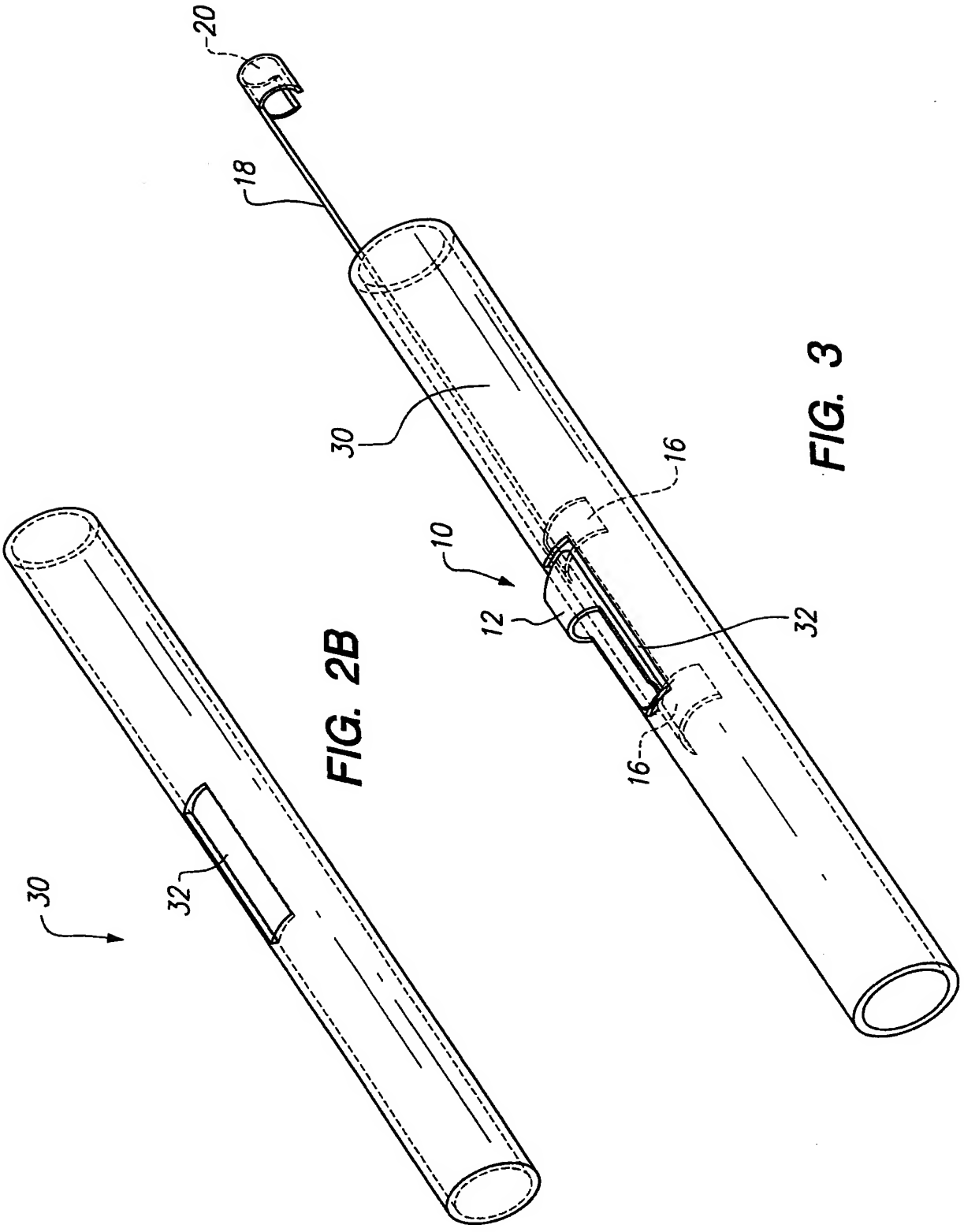

FIG. 2B

FIG. 3

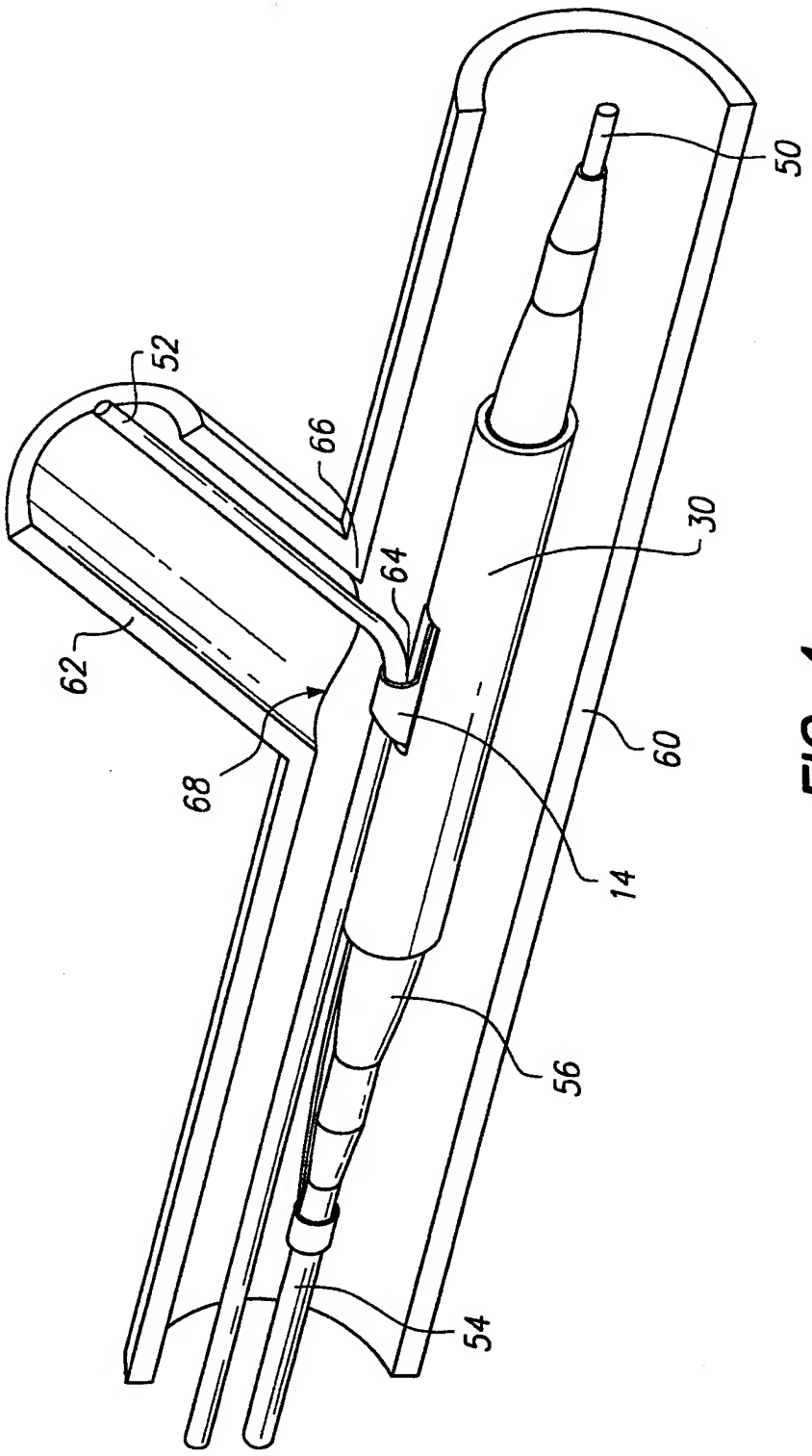

FIG. 4

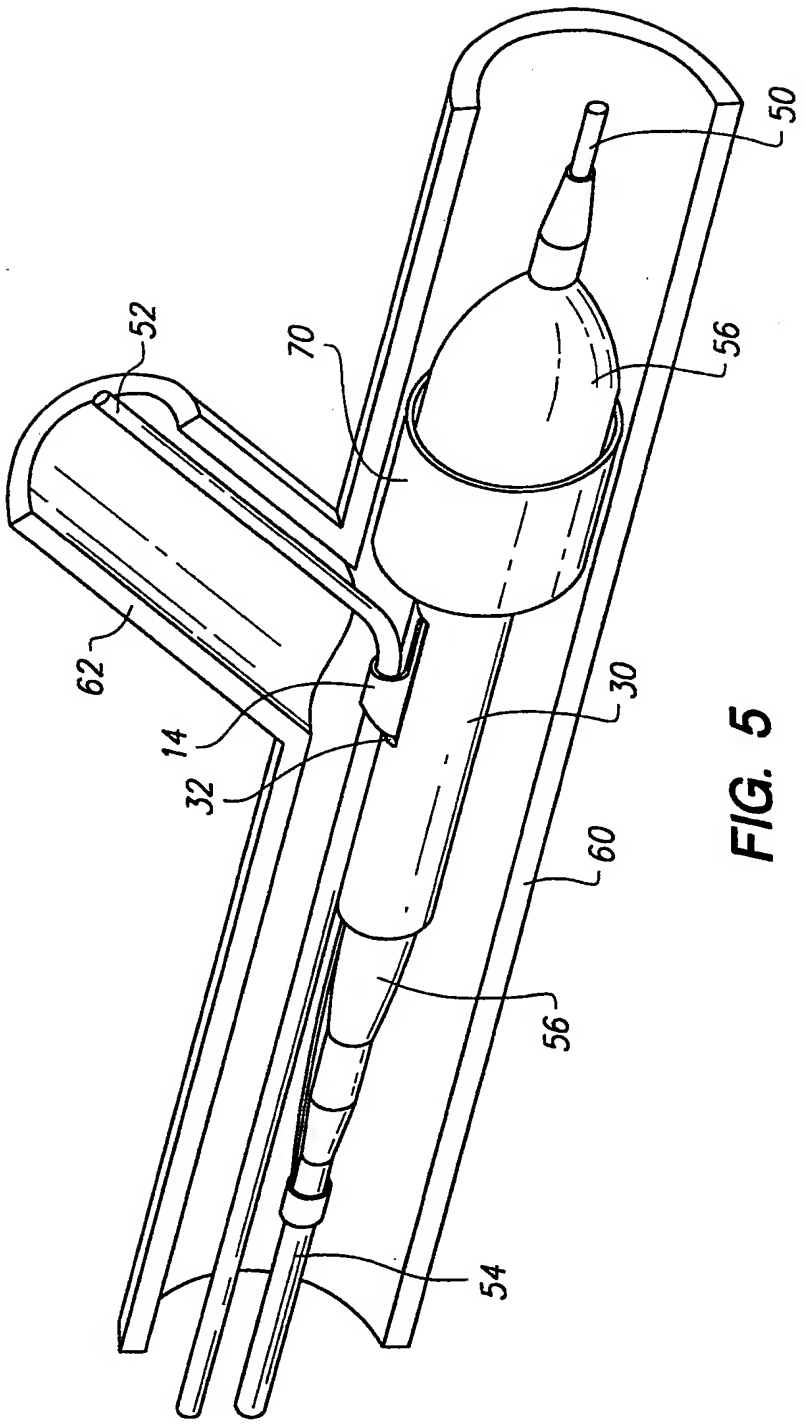

FIG. 5

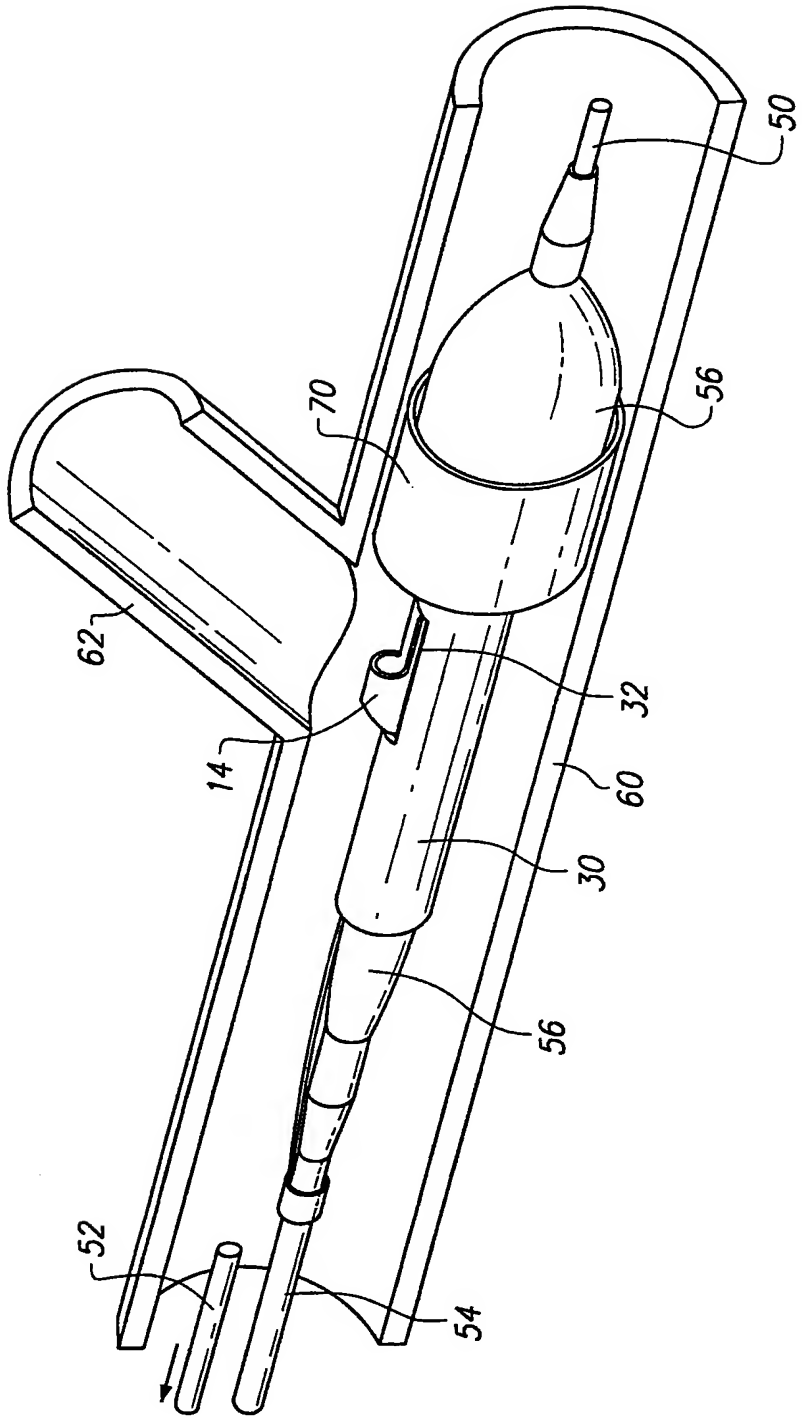

FIG. 6

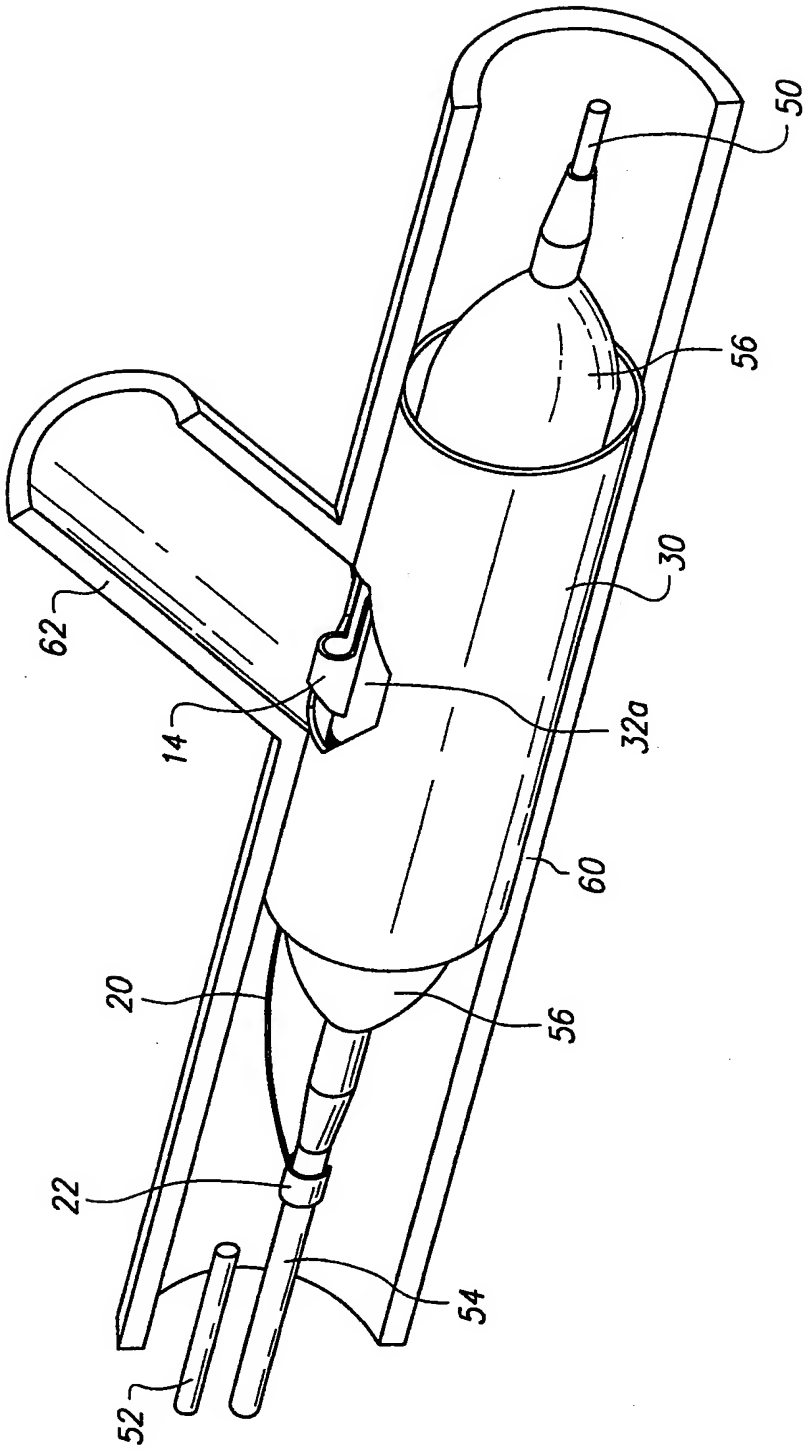

FIG. 7

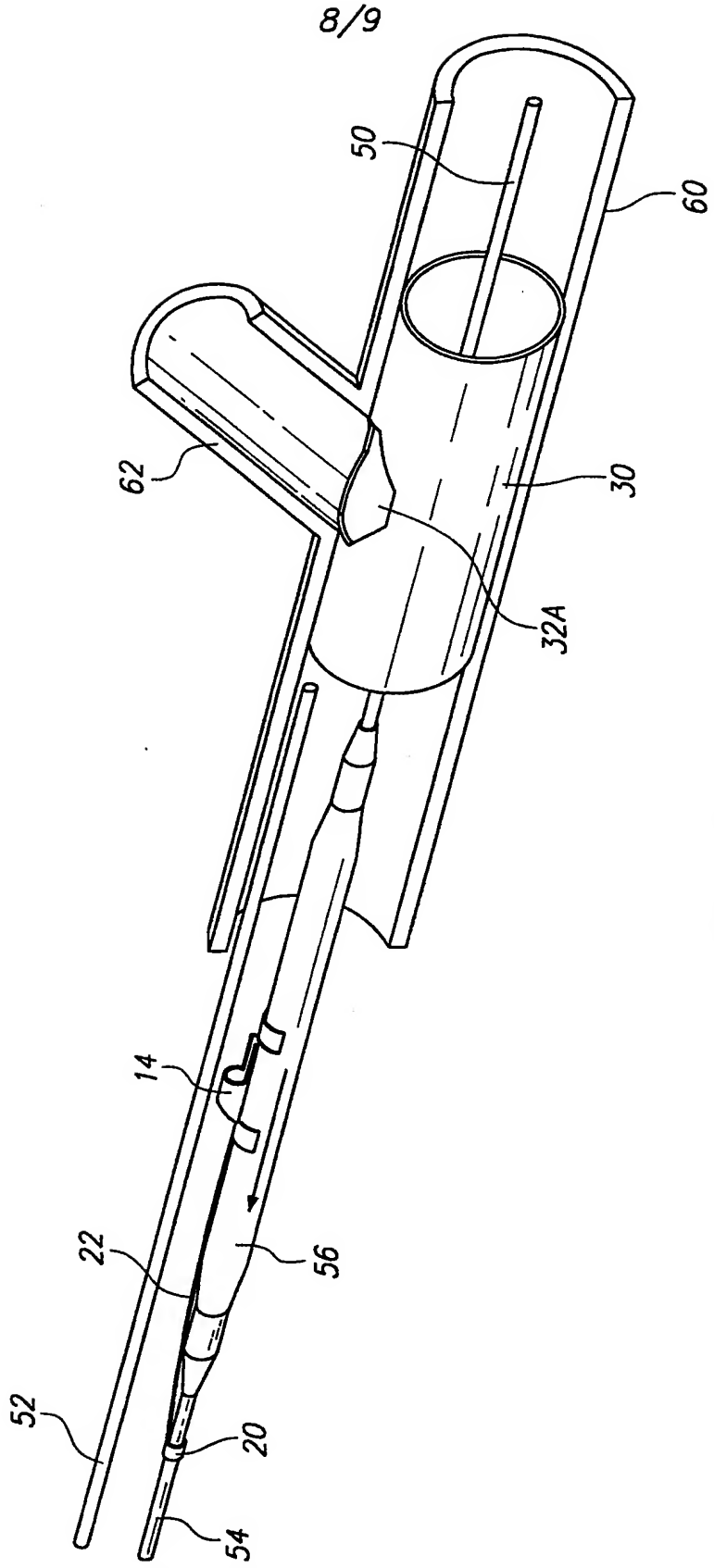

FIG. 8

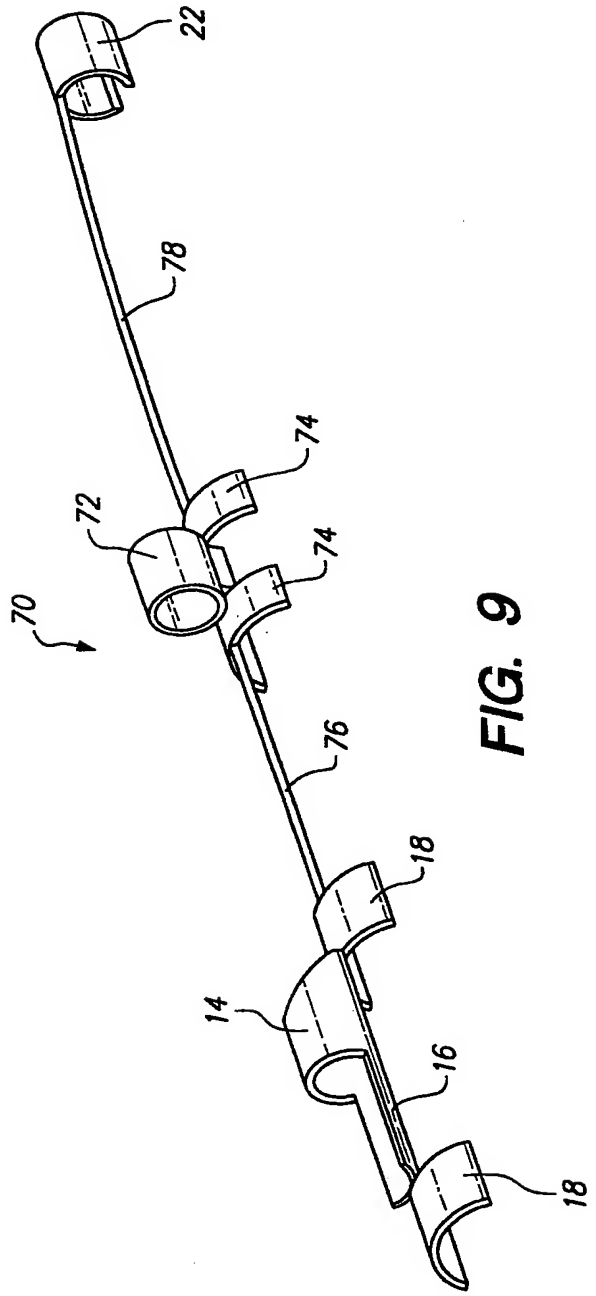

FIG. 9

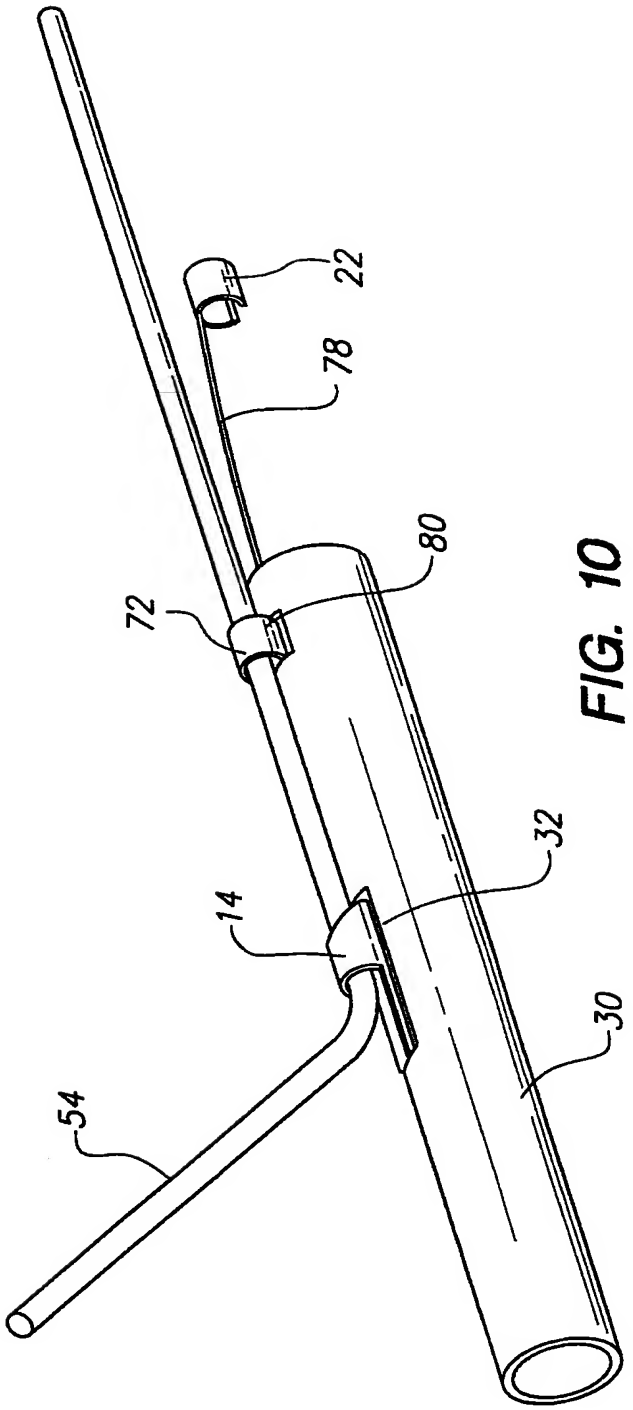

FIG. 10

INTERNATIONAL SEARCH REPORT

Int. tional Application No
PCT/US 00/13264

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 897 700 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 24 February 1999 (1999-02-24)	1,3
A	column 20, line 3 -column 22, line 28; figures 12A-14	9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
1 September 2000	08/09/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Smith, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/US 00/13264

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 897700 A	24-02-1999	JP 11057019 A	02-03-1999

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(71) Applicant *(for all designated States except US)*: ADVANCED STENT TECHNOLOGIES, INC. [US/US]; 7026 Koll Center Parkway, Pleasanton, CA 94566 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: DAVIDSON, Charles, J. [US/US]; 1311 Sunview Lane, Winnetka, IL 60093 (US). VARDI, Gil, M. [US/US]; 14024 Cross Trails Drive, Chesterfield, MO 63017 (US). WILLIAMS, Eric [US/US]; 1125 Davis Street #B-3, Evanston, IL 60201 (US). KAO, Stephen [US/US]; 2330 California Street #29, Mountain View, CA 94040 (US).

(74) Agents: BARRETT, Roger, T. et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111-3834 (US).

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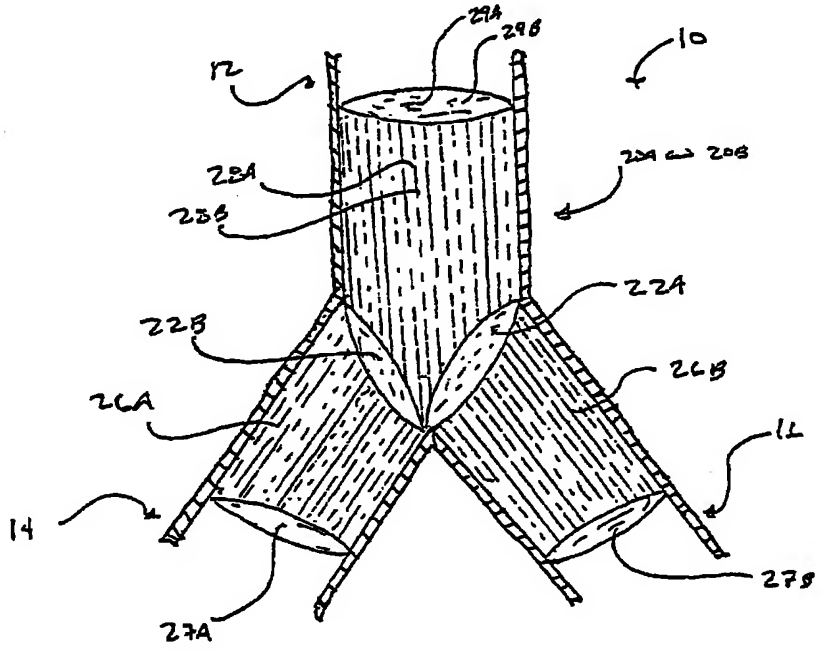
[Continued on next page]

(54) Title: BIFURCATION STENT SYSTEM AND METHOD



(57) Abstract: Methods and apparatus for deploying a stent (20) in a bifurcated body lumen (10). The stent comprises a tubular body defining a lumen therethrough and having a side hole. The tubular body has a first portion (28) with a first wall mass and a second portion (26) with a second wall mass. The first wall mass is less than the second wall mass. When deployed, first portions of two stents overlap in a bifurcated body lumen. The side holes of the two stents are aligned with ostium of branch vessels (14, 16) at a bifurcated body lumen.

WO 01/21095 A2

patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BIFURCATION STENT SYSTEM AND METHOD

This application claims the benefit of U.S. Provisional Application No. 60/155,611 filed on September 23, 1999, the complete disclosure of which is incorporated herein by reference.

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is being filed concurrently with related U.S. Patent App. Serial No. _____ (Attorney Docket Number 019601-000420), entitled "Stent Range Transducers and Methods of Use"; and U.S. Patent App. Serial No. _____ (Attorney Docket Number 019601-000410), entitled "Differentially Expanding Stent and Methods of Use", the complete disclosures of which are incorporated herein by reference and filed at a date even herewith.

TECHNICAL FIELD

The present invention relates to stents, stent systems, and methods for delivery and use thereof.

BACKGROUND OF THE INVENTION

A type of endoprosthesis device, commonly referred to as a stent, may be placed or implanted within a vein, artery or other body lumen for treating occlusions, stenoses, or aneurysms of a vessel by reinforcing the wall of the vessel or by expanding the vessel. Stents have been used to treat dissections in blood vessel walls caused by balloon angioplasty of the coronary arteries as well as peripheral arteries and to improve angioplasty results by preventing elastic recoil and remodeling of the vessel wall. Two randomized multicenter trials have recently shown a lower restenosis rate in stent treated coronary arteries compared with balloon angioplasty alone (*Serruys, PW et al.*, New England Journal of Medicine 331: 489-495 (1994) and *Fischman, DL et al.* New England Journal of Medicine 331:496-501 (1994)). Stents have been successfully implanted in the urinary tract, the bile duct, the esophagus and the tracheo-bronchial tree to reinforce those body organs, as well as implanted into the neurovascular, peripheral vascular, coronary,

cardiac, and renal systems, among others. The term "stent" as used in this Application is a device which is intraluminally implanted within bodily vessels to reinforce collapsing, dissected, partially occluded, weakened, diseased or abnormally dilated or small segments of a vessel wall.

One of the drawbacks of conventional stents is that they are difficult to position in and around vessel bifurcations (branch points). Often treatment of diseased vessels at or near bifurcations requires placement of a stent in both a main vessel and a branch vessel at the bifurcation. In general, placement of stents in both the branch and main vessels involves positioning a main stent adjacent to a bifurcation such that an aperture in a side of the stent aligns with the ostium of a branch vessel. Then, a branch stent is positioned through the aperture and in the branch vessel. The branch stent is then attached to the main stent at the aperture.

Because this type of positioning and attachment can be difficult, it may provide suboptimal results. For example, if the branch stent is not properly attached, it may not adequately cover an area near the bifurcation. Further, if the branch stent remains substantially disposed within the main stent such that the main and branch stents overlap, there is risk that restenosis will occur due to metal burden.

In light of the foregoing, it would be desirable to provide advanced methods and/or apparatus to treat body lumens at or near bifurcations.

SUMMARY OF THE INVENTION

The invention provides methods, systems and apparatus for positioning a stent in a bifurcated body lumen. The methods, systems and apparatus may be used to support three branches of a bifurcated body lumen. In one aspect of the invention, two identical stents can be used to support the three branches.

In one particular embodiment, a stent for placement in a bifurcated body lumen comprises a tubular body defining a lumen therethrough and having a side hole. The tubular body has a first portion with a first wall mass and a second portion with a second wall mass. The second wall mass is greater than the first wall mass.

In some embodiments of the invention the first wall mass is approximately one-half the second wall mass. Thus, when two first portions of two stents are overlapped, the wall mass of the combined two first portions approximately equals that of the second portion of a single stent.

In another embodiment of the invention, a stent system for placement in a bifurcated body lumen is provided. The bifurcated body lumen has a main vessel and first and second branch vessels. The system comprises a first stent body including a first portion, a second portion, and a side hole. The system further includes a second stent body with a first portion, a second portion, and a side hole. The first portion of the first stent body is disposed within and generally coaxially aligned with the first portion of the second stent body. The second portion of the first stent body extends through the side hole of the second stent body.

In yet another embodiment, a method for deploying a stent in a bifurcated body lumen is provided. The bifurcated body lumen includes a main vessel and first and second branch vessels. The method comprises providing first and second stent bodies each having a first portion, a second portion, and a side hole. The method further comprises positioning the first stent body within the bifurcated lumen such that the first portion is positioned within the main vessel and the second portion is positioned within the first branch vessel. The second stent body is positioned such that the first portion is generally aligned with and within the first portion of the first stent body within the main vessel, and the second portion extends through the side hole of the first stent body and into the second branch vessel. Both the first and second stent bodies are expanded.

Some embodiments of the method involve aligning the side hole of the first stent body with an ostium of the second branch vessel. Also, alignment of the side hole of the second stent body with an ostium of the first branch vessel is provided.

In still another embodiment, a kit comprising a stent along with instructions for use is provided. The instructions set forth a method for positioning the stent in a bifurcated body lumen.

Reference to the remaining portions of the specification, including the drawings and claims, will realize other features and advantages of the present invention. Further features and advantages of the present invention, as well as the structure and operation of various embodiments of the present invention, are described in detail below with respect to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a Y-shaped bifurcation in a body lumen for treatment with apparatus, systems and methods of the present invention;

Figs. 2A and 2B depict overall views of two embodiments of a stent according to the present invention;

Figs. 3A through 3C illustrate three embodiments each providing a differential wall mass between portions of the stent illustrated in Figs. 2A and 2B;

Figs. 4A through 4C show a "rolled out" view of three alternative strut patterns which can be used according to the present invention;

Figs. 5A through 5C illustrate an embodiment comprising stent placement in the Y-shaped bifurcation of Fig. 1; and

Fig. 6 shows a kit including a stent according to the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The invention provides methods, systems and apparatus for positioning a stent in a bifurcated body lumen. The methods, systems and apparatus may be used to support three or more branches of a bifurcated body lumen.

Applications of the invention include insertion into a body lumen including, among others, the cardiac, coronary, carotid artery, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain. The invention is particularly useful in applications involving Y-shaped bifurcations as illustrated in Fig. 1. A Y-shaped bifurcation 10 includes a main vessel 12, a left vessel 14 defining a left ostium 15, and a right vessel 16 defining a right ostium 17. It will be appreciated by those skilled in the art that left and right are arbitrary terms, and other configurations are within the scope of the present invention.

Referring now to Fig. 2A, an embodiment of a stent 20 includes an outer wall 21, a distal orifice 27, and a proximal orifice 29. Outer wall 21 includes a distal portion or end 26 and a proximal portion or end 28. Further, an interface 24 exists at a junction of distal end 26 and proximal end 28. Use of the term wall is not intended to limit stent 20 to solid, non-porous walls. Stent outer wall 21 preferably comprises a mesh-like structure as further described below. In this embodiment, stent 20 includes a side hole 22 formed in distal end 26. In an alternative embodiment shown in Fig. 2B, stent 20 includes side hole 22 formed partially in distal end 26 and partially in proximal end 28.

In some embodiments, a balloon 25 is disposed through the center of outer wall 21. As balloon 25 is inflated, it exerts pressure on outer wall 21 causing stent 20 to

expand. It should be appreciated that other devices for exerting pressure on outer wall 21 can be used. Alternatively, in one embodiment, no device for exerting pressure on outer wall 21 is required as stent 20 is designed to expand without application of pressure, such as when stent 20 is released from a sheath.

In one embodiment of the invention, two identical stents 20 are positioned in Y-shaped bifurcation 10 and subsequently deployed. The stents 20 are positioned such that each of main vessel 12, left vessel 14, and right vessel 16 are supported near the bifurcation. When positioned, the two stents 20 overlap at their proximal ends 28 in main vessel 12. Distal end 26 of one stent is disposed in left vessel 14 and distal end 26 of the other stent is disposed in right vessel 16.

Distal end 26 of stent 20 is comprised of sufficient wall mass to support either left vessel 14 or right vessel 16 when deployed in the respective vessel. In contrast, wall mass of proximal end 28 is less than distal end 26. The reduced wall mass is designed such that when two proximal ends 28 overlap in main vessel 12, their combined wall mass is sufficient to support main vessel 12. Further, the wall mass of proximal end 28 is designed such that overlapping two proximal ends 28 in main vessel 12 does not cause metal burden on the stented body. In one particular embodiment, the wall mass of distal end 26 is approximately twice the wall mass of proximal end 28. Thus, when two proximal ends 28 overlap in main vessel 12, the wall mass in main vessel 12 approximately equals the wall mass in either left vessel 14 or right vessel 16.

Thus, the invention advantageously allows for overlapping stents near a bifurcation without causing metal burden on the stented body. This elimination of metal burden reduces the risk of restenosis.

As used herein, wall mass indicates a material density per surface area of outer wall 21. Accordingly, wall mass is a function of the material and/or geometry used to form outer wall 21. For example, increasing the thickness of outer wall 21 results in an increased wall mass. Further, using a higher density material also increases wall mass. Stent 20 may comprise, but is not limited to, stainless steel, nitinol, titanium, and the like.

As used herein, side hole 22 in stent 20 is a relatively large hole which is intended to be aligned with the ostium of a branch vessel. Such a side hole is separate from any of the multiple passageways extending through the side of stent 20 between struts in the stent geometry. Accordingly, side hole 22 is a hole which is understood to be larger than other passages through stent 20. In some embodiments, side hole 22 is defined by a band of continuous material which defines the perimeter of side hole 22.

This continuous band of material preferably comprises discontinuities over its length so that the area of side hole 22 expands together with the expansion of stent 20.

It should be appreciated that the location of side hole 22 relative to distal end 26 and proximal end 28 can be varied. In some embodiments, side hole 22 is located such that only areas of outer wall 21 with reduced wall mass will overlap corresponding areas of another stent when side hole 22 is aligned with the ostium of a branch vessel.

It also should be appreciated that two identical stents 20 can be used to support main vessel 12, left vessel 14, and right vessel 16 near a bifurcation. Using two identical stents 20 reduces both manufacturing costs and insertion complexity. Further, two identical delivery systems may be used which further reduces manufacturing costs and insertion complexity.

Three embodiments for providing a differential wall mass between proximal end 28 and distal end 26 are illustrated in Figs. 3A through 3C. It should be recognized that these forms are merely illustrative and that many other embodiments for providing differential wall mass are possible according to the present invention.

Fig. 3A illustrates an embodiment of a portion 30 of stent 20. Portion 30 includes interface 24 at a junction between a distal portion 32 and a proximal portion 34. While junction 24 is depicted as a linear junction 24, junction 24 may have other shapes, including irregular and nonlinear shapes in this and other embodiments. Distal portion 32 is formed from struts 36 and proximal portion 34 is formed from struts 38. Struts 36 are similar in thickness, but wider than struts 38. Due to the larger width of struts 36, the wall mass of distal portion 32 is greater than the wall mass of proximal portion 34. In a preferred embodiment, struts 36 are of similar thickness and approximately twice as wide as struts 38. Thus, when two proximal portions 34 overlap, their combined wall mass is roughly equivalent to the wall mass at distal portion 32.

Fig. 3B illustrates an embodiment of a portion 40 of stent 20. Portion 40 includes interface 24 at a junction between a distal portion 42 and a proximal portion 44. Distal portion 42 is formed from struts 46 and proximal portion 44 is formed from struts 48. The geometry of struts 46 and 48 are similar, but the density per surface area of struts 46 is higher than a corresponding density for struts 48. This density of struts per surface area is also known as cell density. Due to the higher cell density in distal portion 42, distal portion 42 has a higher wall mass than proximal portion 44. In a preferred embodiment, the cell density in distal portion 42 is approximately twice the cell density in

proximal portion 44. Thus, when two proximal portions 44 overlap, their combined wall mass is roughly equivalent to the wall mass at distal portion 42.

Fig. 3C illustrates an embodiment of a portion 50 of stent 20. Portion 50 includes interface 24 at a junction between a distal portion 52 and a proximal portion 54. Distal portion 52 is formed from struts 56 and proximal portion 54 is formed from struts 58. For clarity of illustration, only struts 56 and 58 on the top and bottom of stent 20 are shown, however, it should be understood that proximal portion 54 includes other struts 58 and that distal portion 52 includes other struts 56. Struts 56 are similar in width, but wider than struts 58. Thus, outer wall 21 of stent 20 is thicker at distal portion 52 than at proximal portion 54. Due to the greater thickness, the wall mass of distal portion 52 is greater than the wall mass of proximal portion 54. In a preferred embodiment, struts 56 are of similar width and approximately twice as thick as struts 58. Thus, when two proximal portions 54 overlap, their combined wall mass is roughly equivalent to the wall mass at distal portion 52.

From the foregoing discussion, it should be apparent that many combinations of materials, strut structure, and strut geometry can be used in accordance with the invention. For example, a structure including struts at proximal end 28 that are both wider and thicker than struts at distal end 26 could be used to provide a differential wall mass.

Further, it should be recognized that a number of strut patterns can be used to form both distal end 26 and proximal end 28. For example, Figs. 4A through 4C illustrate three alternative strut patterns which can be used according to the invention. Figs. 4A through 4C and the corresponding written description are adapted from U.S. Patent App. Serial No. 09/600,348 (Attorney Docket No. 19601-000120), the complete disclosure of which is incorporated herein by reference.

Referring to Fig. 4A, a stent pattern 100 is illustrated in a "rolled out" view, i.e., a tubular stent is broken along an axial line and then rolled out to show stent pattern 100. Stent pattern 100 is illustrated prior to expansion. Stent pattern 100 includes a side hole 102 defined by a continuous band 104 having a plurality of loops 106 projecting into the open interior of side hole 102. Loops 106 are an integral part of band 104 and will, prior to expansion or opening, lie within the cylindrical envelope of the tubular body of stent 20. A distal portion 110 of stent pattern 100 lies on one side of side hole 102 and is defined by a plurality of serpentine rings 112. Serpentine rings 112 are joined by axial spring structures 114 so that stent pattern 100 may be bent as stent 20 is

positioned and/or deployed. A proximal portion 120 of stent pattern 100 is formed on the other side of side hole 102. Proximal portion 120 is defined by a plurality of serpentine rings 122 which are generally similar in structure to rings 112 of distal portion 110. Each of the portions 110 and 120 include an axial spine 130 and 132, respectively. Axial spine 130 of distal portion 110 comprises simple W-shaped structures including outermost struts 134 which open at relatively low expansion force on the adjoining hinge regions. In contrast, axial spine 132 of proximal portion 120 comprises box elements 138 which require greater expansion force to open. Thus, during deployment, distal portion 110 will yield first to allow partial opening before proximal portion 120 begins to open.

According to the invention, stent pattern 100 can be formed such that rings 112 are either thicker, wider, or formed at a higher cell density than rings 122. Alternatively, any combination of thickness, width or cell density can be used to provide a differential wall mass between proximal portion 120 and distal portion 110.

A second stent pattern 200 is illustrated in Fig. 4B. A side hole 202 is formed from a continuous band of material, generally as described in relation to Fig. 4A. A distal portion 204 and a proximal portion 206 of stent pattern 200 each comprise a plurality of serpentine ring structures 208 and 210, respectively. While the specific geometries differ, the structures of stent patterns 100 and 200 are generally the same, except for distal spine portion 220 and proximal spine portion 230. Distal spine portion 220 comprises a simple U-shaped loop having a pair of struts joined by a simple C-shaped hinge region. Distal spine portion 220 will thus open at relatively low expansion forces. In contrast, proximal spine portion 230 comprises a serpentine element which allows for axial expansion but does not permit radial expansion. Thus, distal portion 204 will begin opening at much lower expansion forces or pressures than will proximal portion 206.

As with stent pattern 100 and according to the invention, stent pattern 200 can be formed such that rings 208 are either thicker, wider, or formed at a higher cell density than rings 210. Alternatively, any combination of thickness, width or cell density can be used to provide a differential wall mass between proximal portion 206 and distal portion 204.

A third stent pattern 300 is illustrated in Fig. 4C. Stent pattern 300 comprises a side hole 302 (which is shown in halves in the illustration), a distal portion 304, and a proximal portion 306. Distal portion 304 and proximal portion 306 each comprise serpentine rings 308 and 310, respectively. Serpentine rings 308 and 310 have

different characteristics. More specifically, serpentine rings 308 have axially aligned struts joined by simple hinge regions. The length of the struts is relatively long (compared to those in the proximal region 306 as described below) so that the rings will open at a lower expansion pressure or force. In contrast, serpentine rings 310 of proximal portion 306 have relatively short axial struts defined by hinge regions each having two bands. Such structures require greater expansion force than do serpentine rings 308 of the distal portion 304. Similar to stent patterns 100 and 200, stent pattern 300 can be formed such that wall mass is greater in distal portion 304 than proximal portion 306.

Referring now to Figs. 5A through 5C, a method of deploying stents 20 in Y-shaped bifurcation 10 according to the present invention is described. Two stents 20A and 20B are used to support main vessel 12, left vessel 14, and right vessel 16.

Referring to Fig. 5A, stent 20A is positioned such that proximal end 28A is disposed in main vessel 12 and distal end 26A is disposed in left vessel 14. Side hole 22A is aligned with right ostium 17. Once this alignment is achieved, stent 20A is deployed by expanding the outer wall of stent 20A until both proximal end 28A and distal end 26A contact main vessel 12 and left vessel 14, respectively. After deployment, a passage exists through stent 20A connecting main vessel 12, left vessel 14, and right vessel 16. The passage connecting main vessel 12 and left vessel 14 includes distal orifice 27A and proximal orifice 29A. The passage connecting main vessel 12 and right vessel 16 includes proximal orifice 29A and side hole 22A.

As should be recognized, stent 20A can include structure which conforms to the geometry of main vessel 12 and left vessel 14. The structure further provides access to right vessel 16 through side hole 22A. Thus, when stent 20A is expanded radially outward, it conforms to main vessel 12 and left vessel 14. Such conformity allows stents according to the present invention to fit into different sizes of main 12, left 14, and right 16 vessels.

After deployment of stent 20A, stent 20B is positioned in main vessel 12 and right vessel 16. Fig. 5B illustrates positioning of stent 20B. For clarity of illustration, stent 20A which is positioned according to Fig. 5A is not shown. Stent 20B is positioned such that distal end 26B extends through side hole 22A (not shown) of stent 20A and into right vessel 16. Proximal end 28B is positioned within proximal end 28A (not shown) of stent 20A and main vessel 12. Side hole 22B is aligned with left ostium 15 of left vessel 14. Once this alignment is achieved, stent 20B is deployed by expanding the outer wall of stent 20B until distal end 26B contacts right vessel 16 and proximal end

28B contacts proximal end 28A (not shown) of stent 20A. Thus, a passage exists through stent 20B connecting main vessel 12, left vessel 14 and right vessel 16.

Fig. 5C shows both stent 20A and stent 20B deployed in Y-shaped bifurcation 10. Using the prior discussion in conjunction with Fig. 5C, a passage through stents 20A and 20B connecting main vessel 12, left vessel 14, and right vessel 16 is shown. The passage connecting main vessel 12 and left vessel 14 includes distal orifice 27A, side hole 22B, proximal orifice 29A, and proximal orifice 29B. The passage connecting main vessel 12 and right vessel 16 includes distal orifice 27B, side hole 22A, proximal orifice 29A, and proximal orifice 29B. Further, it is shown that proximal portions 28A and 28B overlap in main vessel 12, while distal portions 26A and 26B are disposed in left vessel 14 and right vessel 16, respectively. As proximal portions 28A and 28B comprise reduced wall mass, overlapping portions 28A and 28B provides similar coverage to main vessel 12 as is provided in left vessel 14 and right vessel 16. Of course, it should be appreciated that stent 20B can be positioned and deployed prior to positioning and deploying stent 20A. Further, it should be appreciated that either stent 20A and/or stent 20B can be positioned by advancing through main vessel 12, left vessel 14, or right vessel 16 toward Y-shaped bifurcation 10.

Another embodiment provides for positioning stent 20A in main vessel 12 and left vessel 14 followed by partial deployment of stent 20A. After stent 20A is partially deployed, stent 20B is positioned such that proximal end 28B is disposed within proximal end 28A of stent 20A and distal end 26B is disposed in right vessel 16. After positioning stent 20B, both stent 20A and stent 20B are fully deployed.

In yet another embodiment, stent 20A includes a balloon 25 disposed therethrough. Stent 20A, including balloon 25 are positioned according to the discussion above. Balloon 25 is then inflated causing stent 20A to deploy. Balloon 25 is then deflated and removed from stent 20A. Stent 20B, including a similar balloon 25 or the same balloon 25, is then positioned according to the previous discussion. Balloon 25 is then inflated causing stent 20B to deploy. After deployment, balloon 25 is removed and stents 20A and 20B remain deployed as shown in Fig. 5C.

In still another embodiment, stent 20B is partially disposed within stent 20A prior to positioning within vessel 12. Together, both stent 20A and 20B are positioned in main vessel 12 near Y-shaped bifurcation 10. Stent 20A, with stent 20B partially disposed within, is located such that side hole 22A aligns with right ostium 17. Stent 20A is then partially expanded. Then, stent 20B is positioned through side hole

22A such that proximal end 28B is approximately concentric with and within proximal end 28A and distal end 26B is located in right vessel 16. Both stent 20A and 20 B are then fully expanded.

In another embodiment (not shown in the figures), a first stent 20 including a first and a second side hole could be positioned in main vessel 12 near a bifurcation including a first, second and third branch vessel. The first stent 20 is positioned in main vessel 12 and the first branch vessel such that the first side hole aligns with the ostium of the second branch vessel and the second side hole aligns with the third branch vessel.

A second stent, including a first and a second side hole, is then positioned through the first stent in main vessel 12 and into the second branch vessel by way of the first side hole in the first stent. The first side hole of the second stent is aligned with the ostium of the first branch vessel and the second side hole is aligned with the ostium of the third branch vessel.

Next, a third stent, including a first and a second side hole, is positioned through the first and the second stent in main vessel 12 and into the third branch vessel by way of the aligned second side holes in the first and second stents. The first side hole of the second stent is aligned with the ostium of the first branch vessel and the second side hole is aligned with the ostium of the second branch vessel. Thus, all three branch vessels along with the main vessel are stented. In such a configuration, the three overlapped proximal portions each preferably have about one-third the mass as a corresponding distal portion.

In light of the foregoing description, it should be appreciated that any number of branch vessels could be stented according to the present invention. Further, it should be appreciated that many methods and sequences for positioning and deploying stents 20A and 20B may be provided according to the present invention. For example, U.S. Patent App. Serial No. _____ (Attorney Docket No. 19601-000320), the entire disclosure of which is incorporated herein by reference, describes methods and apparatus for positioning and deploying stents near bifurcations. Further, the referenced application contains details related to aligning stent side holes with ostium of branch vessels. The methods and embodiments provided can be used in accordance with the present invention.

For example, the stent delivery system according to the present invention may employ a moveable or non-moveable side sheath or side member as further

described in U.S. App. Serial No. _____ (Attorney Docket No. 19601-000320), the complete disclosure of which has been previously incorporated by reference. Additionally, for illustration, one embodiment of the referenced application provides an embodiment where a catheter system facilitates placement of the stent within the main vessel, with the side hole being in registry with an ostium of a branch vessel. This placement may be accomplished, for example, by advancing a main vessel guidewire in the main vessel until passing the branch vessel. The catheter is then advanced over the main vessel guidewire until the stent reaches or is proximal to the branch vessel. At this point, a branch vessel guidewire may be introduced through the branch vessel lumen of the catheter. The branch vessel guidewire is advanced out of the catheter and into the branch vessel to assist in aligning the side hole with the ostium of the branch vessel prior to deployment of the stent in the main vessel. To assist in guiding the branch vessel guidewire into the branch vessel, the catheter may taper at a point to a narrow distal end, which may also be curved slightly outwardly. One advantage of such a catheter system is that a single guidewire may be used to introduce the catheter. Once introduced, the catheter serves as a guide for the branch vessel guidewire.

Alignment of the side hole with the ostium can be accomplished in a variety of ways. For example, introduction of the branch vessel guidewire into the branch vessel may sufficiently align the side hole with the ostium. Other alignment techniques may depend on the configuration of the catheter. For example, in some cases the catheter may comprise a flexible sheath that is movably coupled to the catheter body, e.g., by passing through a lumen of a truncated connector that is coupled to the catheter body. Once the branch vessel guidewire is advanced into the branch vessel, the sheath may be advanced into the branch vessel to move the side hole into registry with the ostium.

As shown in Fig. 6, a stent 20 may be conveniently included as part of a kit 400. Conveniently, kit 400 may include most any combination of apparatus and systems discussed herein, along with instructions for use 402 setting forth appropriate procedures for deploying stents using any of the techniques previously described. Instructions for use 402 may be written or in machine readable form. For example, kit 400 may include two stents, 20A and 20B, each crimped over a balloon 25 and coupled to the stent delivery system. The stent delivery system may include catheter 404, a side sheath or member, and/or a proximal hub, among other elements described or incorporated herein. Further, it will be appreciated that kit 400 may alternatively include

any of the other elements described or incorporated herein, and instructions 402 may describe use of any of the other elements.

The invention has now been described in detail for purposes of clarity of understanding. However, it will be appreciated that certain changes and modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A stent for placement in a bifurcated body lumen, said stent comprising:

a tubular body defining a lumen therethrough and having a side hole, said body having a first portion with a first wall mass and a second portion with a second wall mass, wherein said first wall mass is less than said second wall mass.

2. The stent as in claim 1 wherein said first wall mass is about one-half said second wall mass.

3. The stent as in claim 1 wherein said first portion has a first cell density and said second portion has a second cell density, wherein said first cell density is less than said second cell density.

4. The stent as in claim 3 wherein said first cell density is about one-half said second cell density.

5. The stent as in claim 1 wherein said first portion comprises a first plurality of struts and said second portion comprises a second plurality of struts, at least some of said first plurality of struts having a smaller cross-sectional area than said second plurality of struts.

6. The stent as in claim 1 wherein said first portion comprises a first plurality of struts and said second portion comprises a second plurality of struts, said second plurality of struts defining a greater cell density than said first plurality of struts.

7. The stent as in claim 1 wherein said first portion comprises said side hole.

8. The stent as in claim 1 wherein said first portion and said second portion have first and second wall thickness, respectively, said first wall thickness being less than said second wall thickness.

9. The stent as in claim 8 wherein said first wall thickness is about one-half said second wall thickness.

10. A stent system for placement in a bifurcated body lumen having a main vessel and first and second branch vessels, said system comprising:

a first tubular stent body having a first portion and a second portion, said first stent body having a side hole; and

a second tubular stent body having a first portion and a second portion, said second stent body having a side hole;

wherein said first stent body first portion is disposed within and generally coaxially aligned with said second stent body first portion, and said first stent body second portion extends through said side hole of said second stent body.

11. The stent system as in claim 10 wherein said combined first portions comprise about a same mass as one of said second portions.

12. The stent system as in claim 10 wherein said combined first portions comprise a cell density that is about equal to a cell density of one of said second portions.

13. The stent system as in claim 10 wherein said combined first portions have a wall thickness that is about equal to a wall thickness of one of said second portions.

14. The stent system as in claim 10 wherein said combined first portions are adapted to be positioned in said main vessel, said first stent body second portion is adapted to be positioned in said first branch vessel and said second stent body second portion is adapted to be positioned in said second branch vessel.

15. A method for deploying a stent in a bifurcated body lumen having a main vessel and first and second branch vessels, said method comprising:

providing first and second tubular stent bodies each having a first portion, a second portion, and a side hole;

positioning said first stent body within said bifurcated lumen so that said first portion is positioned within said main vessel and said second portion is positioned within said first branch vessel, said positioning further comprising alignment of said first stent body side hole with an ostium of said second branch vessel;

expanding said first stent body.

positioning said second stent body so that said first portion is generally aligned with and within said first stent body first portion in said main vessel, and said second portion extends through said first stent body side hole and into said second branch vessel, said positioning further comprising alignment of said second stent body side hole with an ostium of said first branch vessel; and

expanding said second stent body.

16. The method of claim 15 wherein said expanding said first stent body is performed prior to said positioning said second stent body.

17. The method of claim 15 wherein said combined first portions have about a same mass as one of said second portions.

18. The method of claim 15 wherein said combined first portions have about a same cell density as one of said second portions.

19. The method of claim 15 wherein said first and second stent bodies comprise a metal.

20. A kit comprising:

a stent as in claim 1; and

instructions for use setting forth a method for positioning said stent in a bifurcated body lumen having a main vessel and first and second branch vessels.

Fig 1

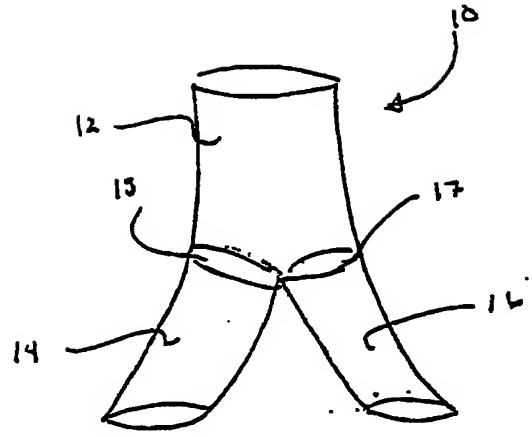


Fig 2A

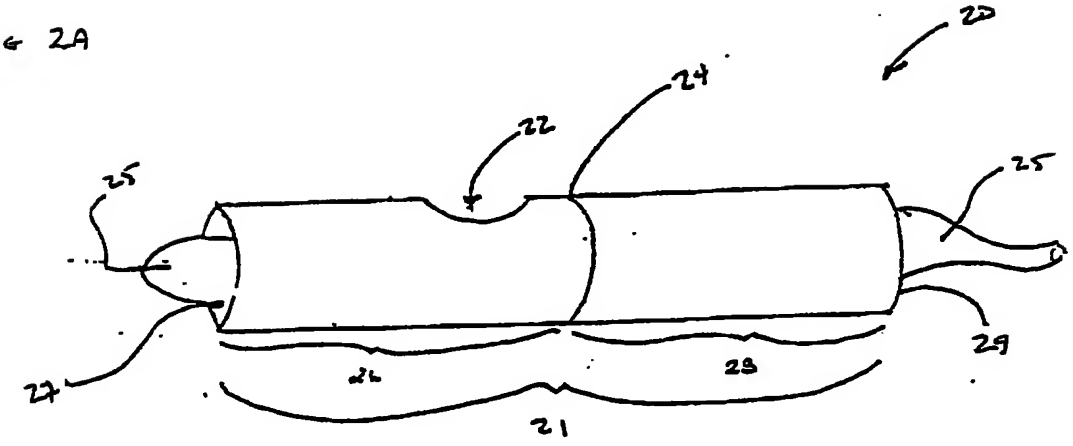


Fig 2B

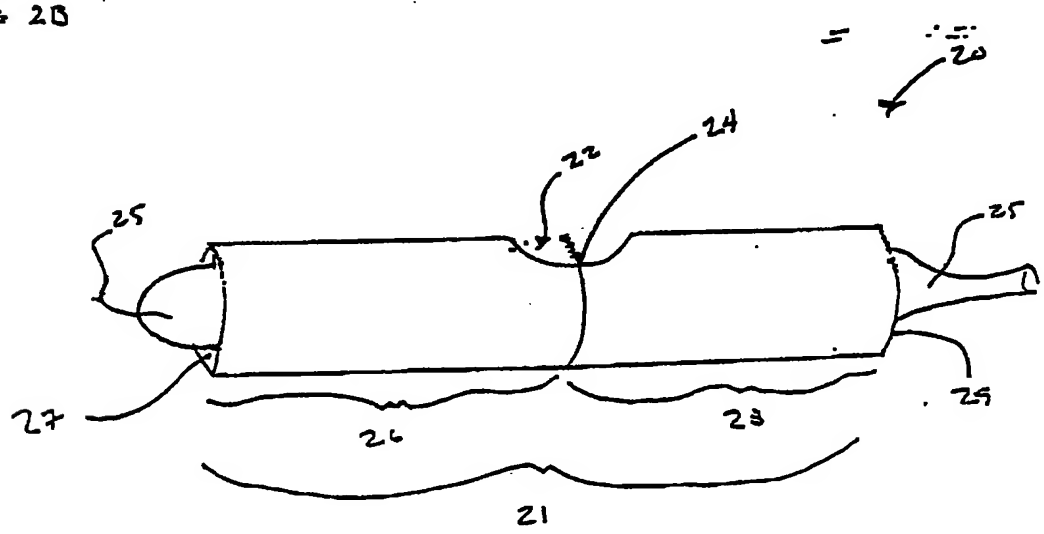


Fig. 3A

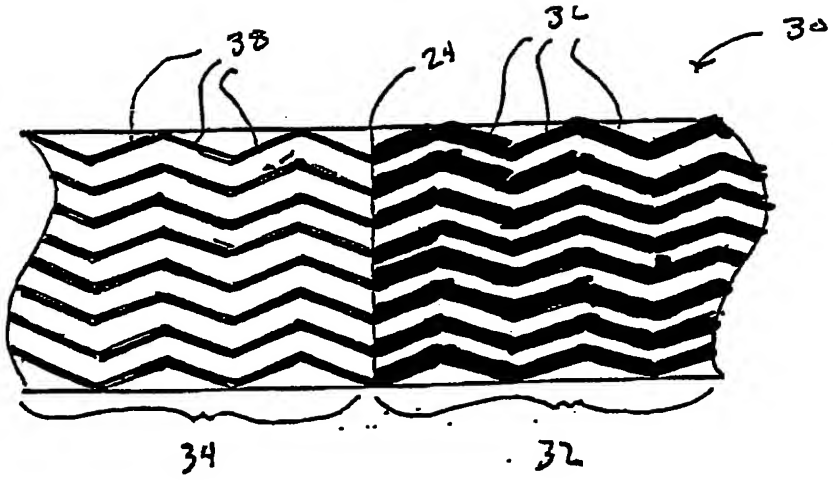


Fig. 3B

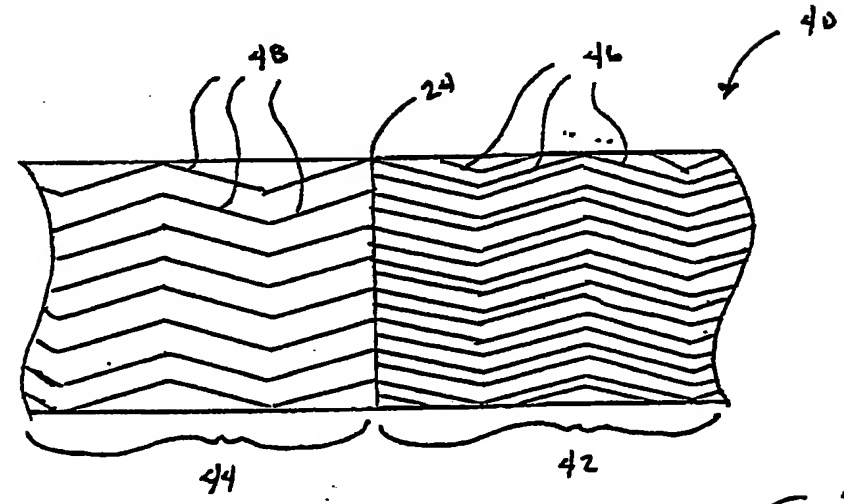
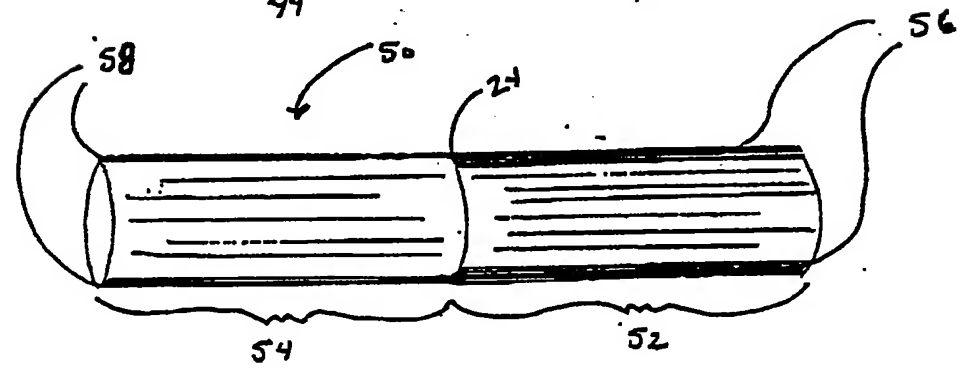


Fig. 3C



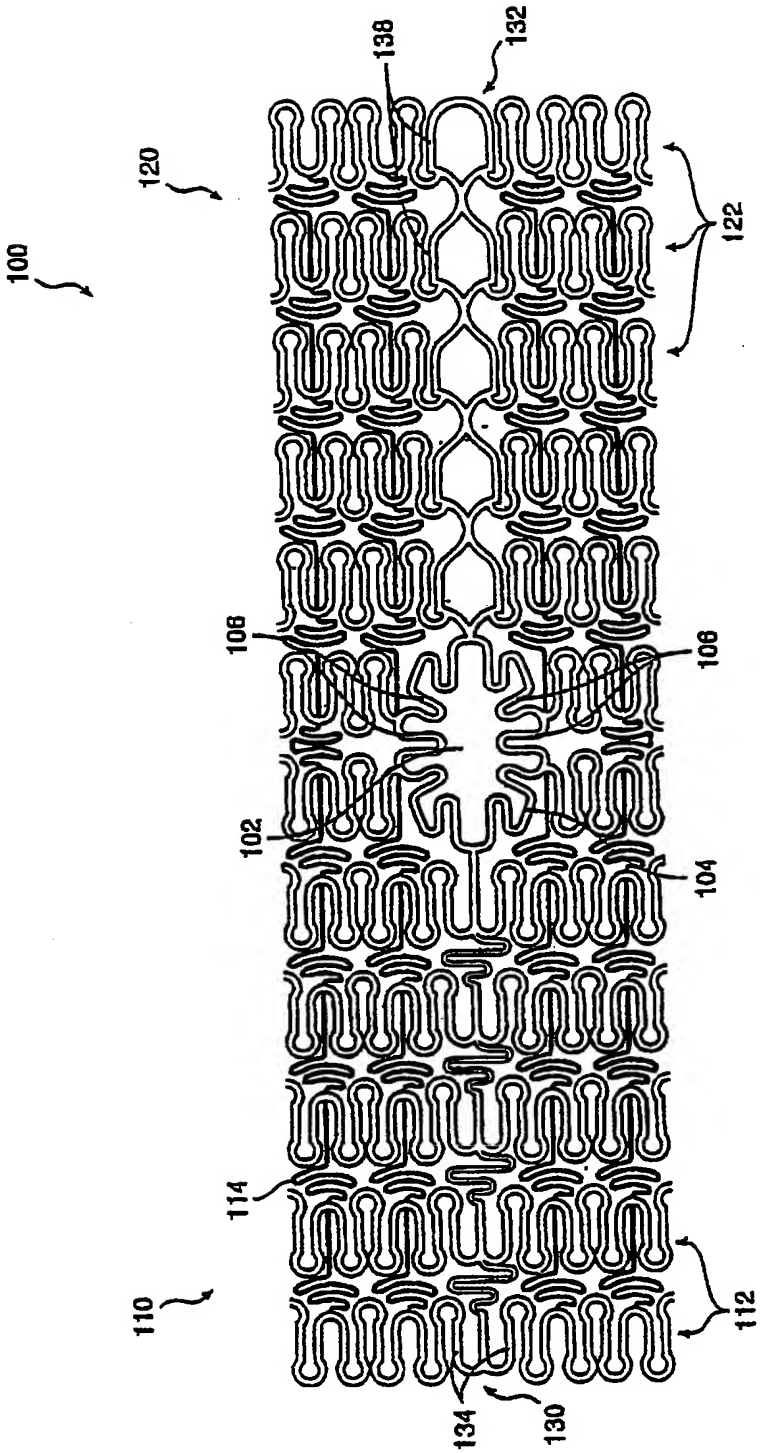


FIG. 4A

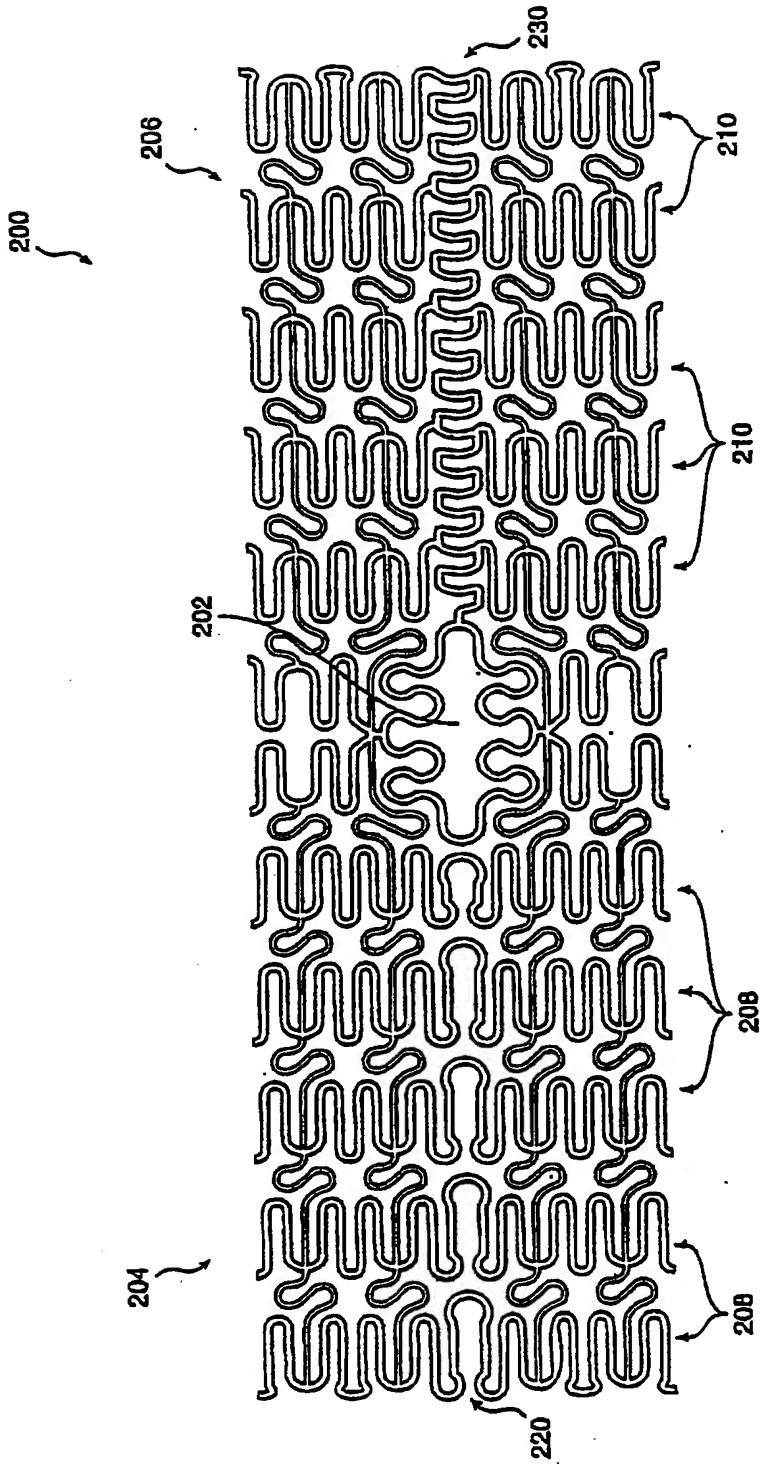


FIG. 4B

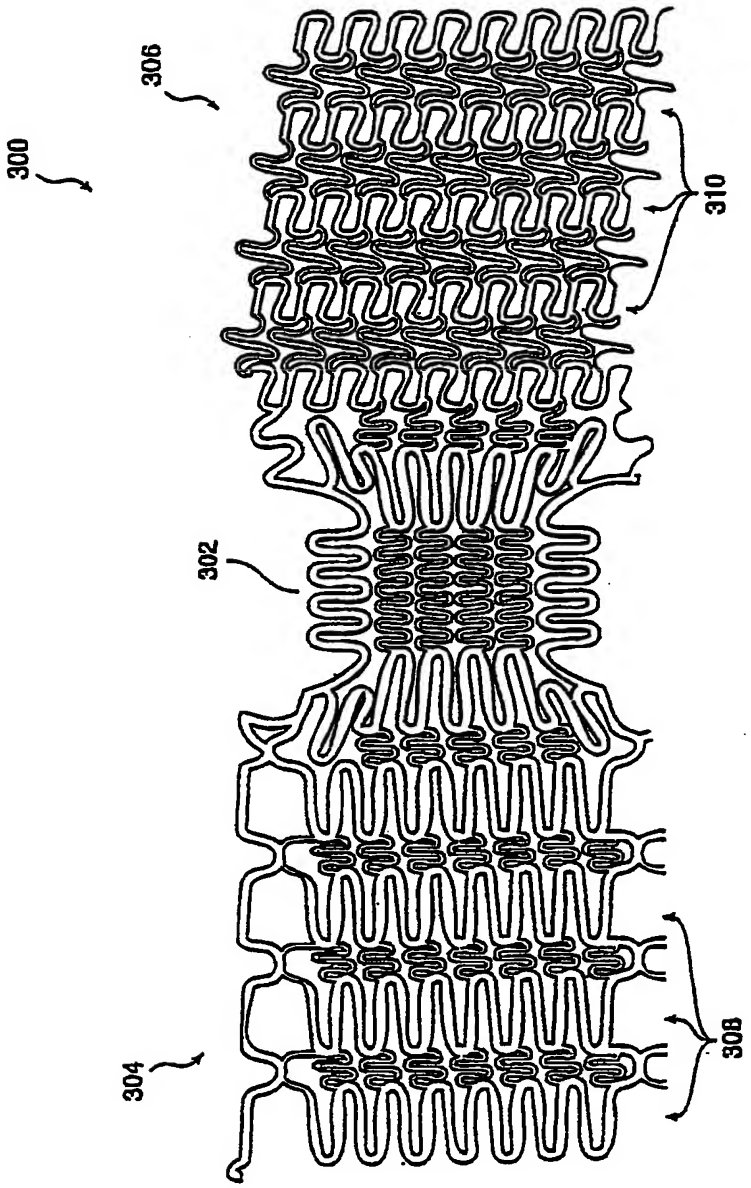


FIG. 4C

Fig 5A

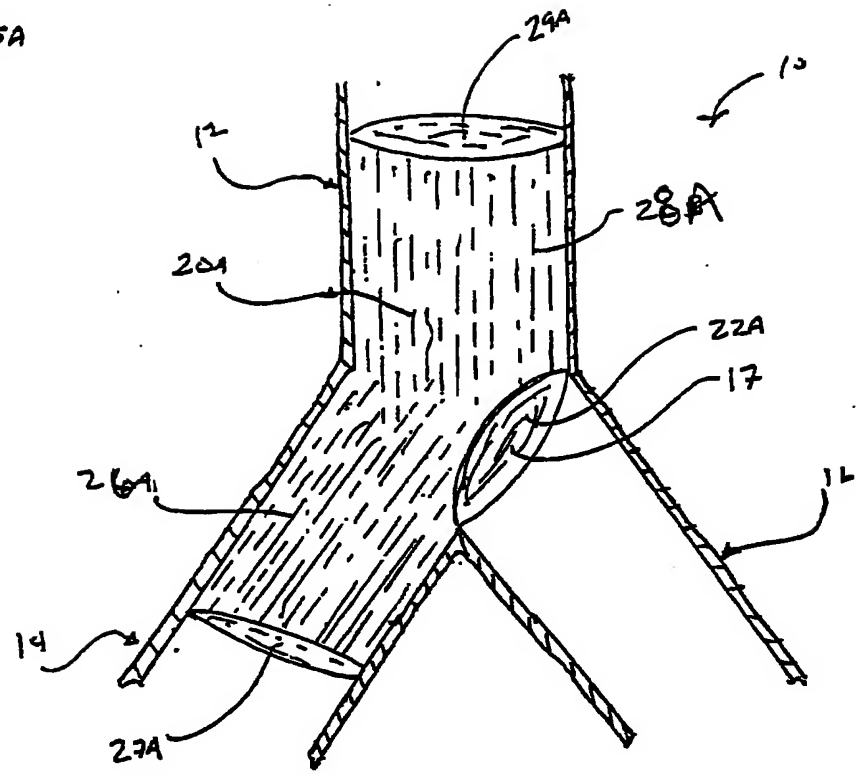
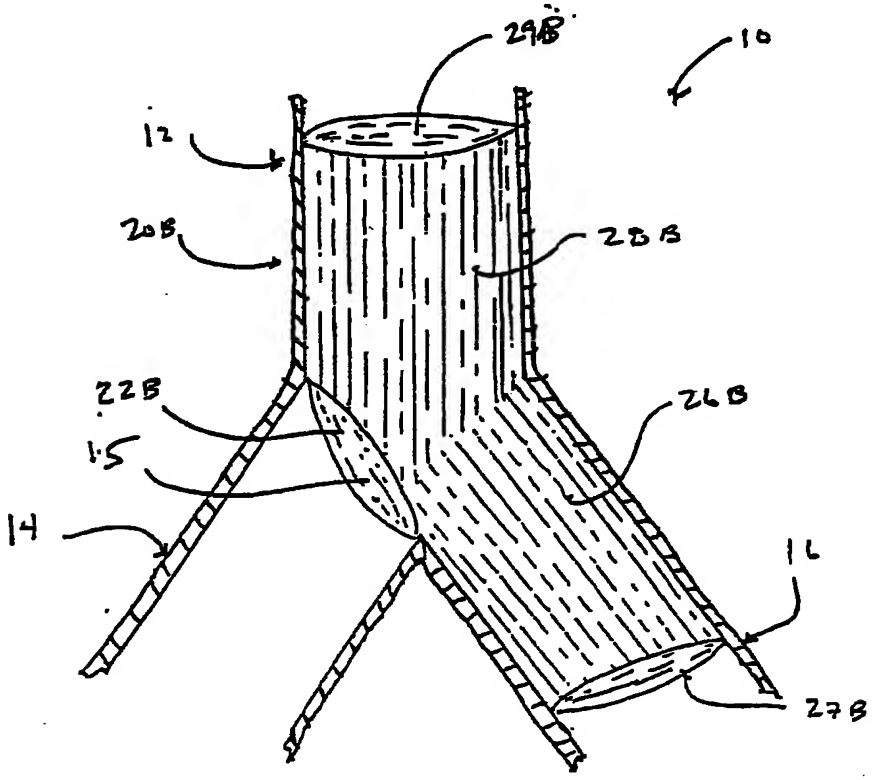

29A
10
12
28A
20A
22A
17
26A
16
14
27A

Fig 5B


29B
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12
20B
28B
22B
26B
15
14
16
27B

FIG. 5C

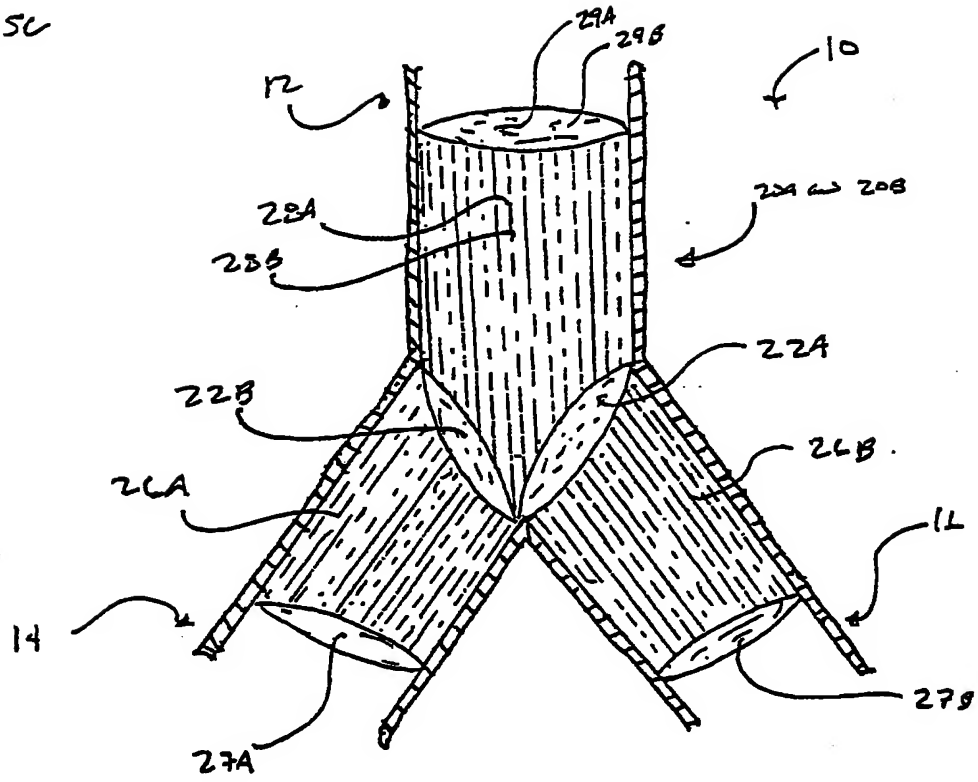
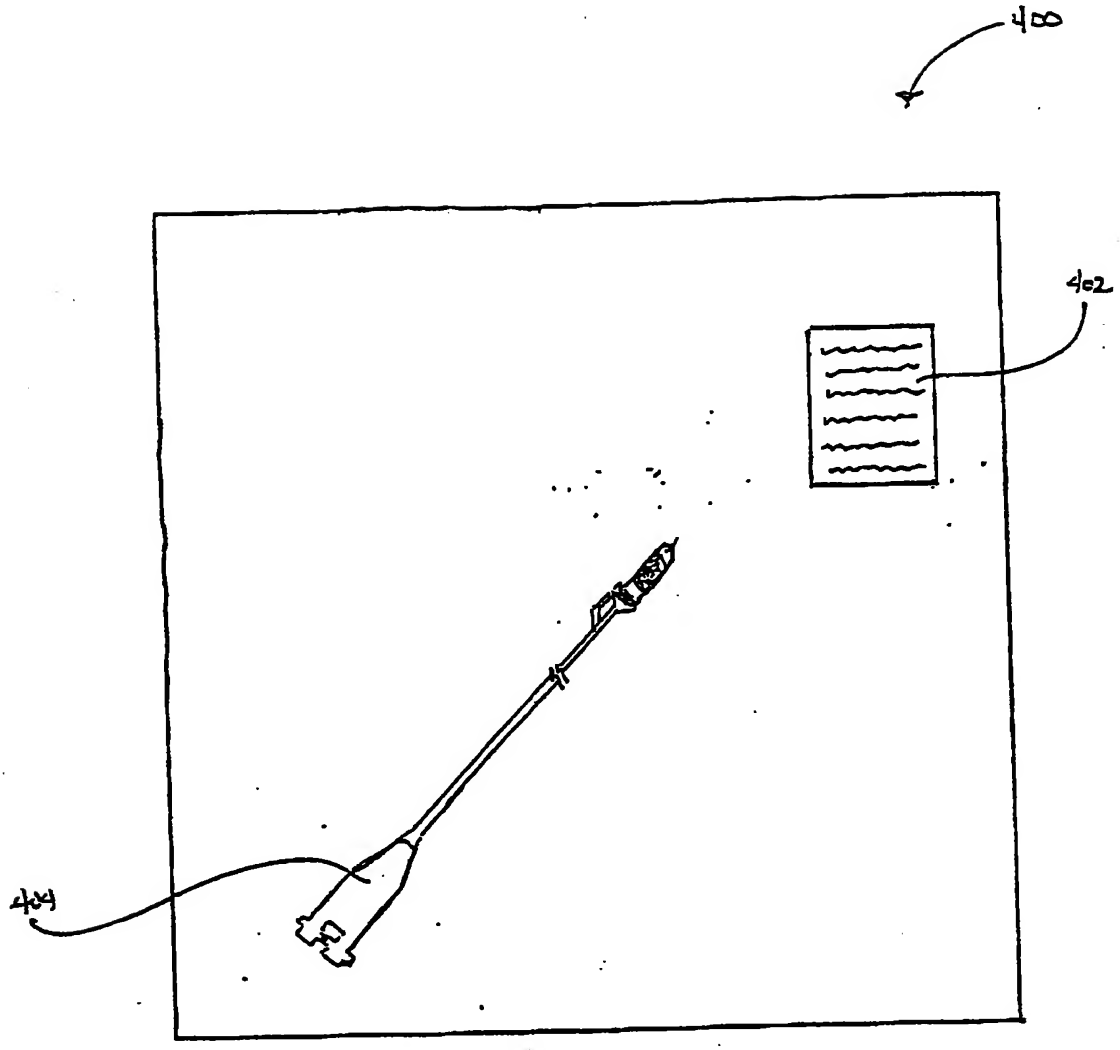


Fig 6.



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(71) Applicant *(for all designated States except US)*: **ADVANCED STENT TECHNOLOGIES, INC.** [US/US]; 7026 Koll Center Parkway, Pleasanton, CA 94566 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DAVIDSON, Charles, J.** [US/US]; 1311 Sunview Lane, Winnetka, IL 60093 (US). **VARDI, Gil, M.** [US/US]; 14024 Cross Trails Drive, Chesterfield, MO 63017 (US). **WILLIAMS, Eric** [US/US]; 1125 Davis Street #B-3, Evanston, IL 60201 (US). **KAO, Stephen** [US/US]; 2330 California Street #29, Mountain View, CA 94040 (US).

(74) Agents: **BARRETT, Roger, T.** et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111-3834 (US).

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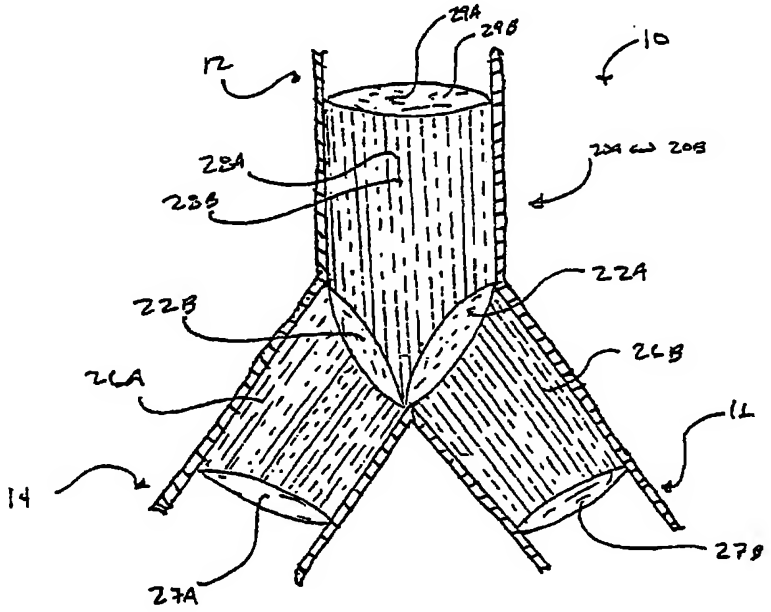
[Continued on next page]

(54) Title: BIFURCATION STENT SYSTEM AND METHOD



(57) Abstract: Methods and apparatus for deploying a stent (20) in a bifurcated body lumen (10). The stent comprises a tubular body defining a lumen therethrough and having a side hole. The tubular body has a first portion (28) with a first wall mass and a second portion (26) with a second wall mass. The first wall mass is less than the second wall mass. When deployed, first portions of two stents overlap in a bifurcated body lumen. The side holes of the two stents are aligned with ostium of branch vessels (14, 16) at a bifurcated body lumen.

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US CL :623/1.11-1.15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.11-1.15

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,755,771 A (PENN ET AL.) 26 MAY 1998 FIG. 1-2, 7	1-14 --- 15-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Name and mailing address of the ISA/US
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Box PCT
Washington, D.C. 20231
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